EXHIBIT E

(PART II)

[HN31] Even if Plaintiff cannot prove scienter through evidence of motive and opportunity, evidence of conscious misbehavior or recklessness may suffice. See *GSC Partners CDO Fund v. Washington, 368 F.3d at 238-39 (3d Cir. 2004)*. "'Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious [or reckless] behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater.'" *Id., 368 F.3d at 238* (quoting *Kalnit, 264 F.3d at 142*). In the context of securities fraud, a reckless statement is one representing "'an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known [*80] to the defendant or so obvious that the actor must have been aware of it.'" *Advanta 180 F.3d at 535* (quoting *McLean v. Alexander, 599 F. 2d 1190, 1197 (3d Cir. 1979))*. "An egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference . . . of recklessness." *Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000)*(citing *Chill v. General Elec. Co., 101 F.3d 263, 269 (2d Cir. 1996))* (quoting *Goldman v. McMahan, Brafman, Morgan & Co., 706 F. Supp. 256, 259 (S.D.N.Y. 1989))* (omission in original). At the same time, however, corporate officials "need not present an overly gloomy or cautious picture." *Novak, 216 F.3d 300, 309* (citations omitted).

Defendants argue that conscious misbehavior or recklessness cannot be inferred because each of the eleven challenged First Class Period statements -- each implying or stating that "Vanlev had been shown to be effective, to be generally safe and well tolerated and to present a risk of angioedema similar to competing agents"-- were made with "every reason to believe that [they] were true or were opinions [*81] reasonably based on facts." Defs.' Mem. at 8-9; Defs.' 56.1. P162.

Defendants' Evidence: Defendants cite the following evidence to show that the early clinical trials supported the truth of the challenged statements:

. expert opinions that the early clinical trials demonstrated that Vanlev was more effective than widely prescribed ACE inhibitors at reducing blood pressure in hypertensive patients, see Defs.' 56.1 P163 (citing DX 11 PP17, 18; DX 22 P26);

. report of the Bristol-Myers Squibb, Pharmaceutical Research Institute, "Integrated Summary of Safety for Omapatrilat," final draft dated November 22, 1999, which states in the "Summary and Conclusions" section that "omapatrilat was safe and well tolerated in subjects with hypertension at doses of up to 80mg once daily, with a rate of adverse events and *discontinuation due to adverse events similar to established antihypertensive agents* . . .," see id. (citing DX 282:163-64) (emphasis added);

. an abstract published in the February 2000 Supplement to the Journal of the American College of Cardiology, intended for reference at the 49th Annual Scientific Session, where Dr. Pouler was scheduled to give [*82] an oral presentation, discussing the results obtained from Omapatrilat in the pre-OVERTURE heart failure trails, stating that "OMA improved the combined endpoint of death or hospitalization for worsening [heart failure] . . . Both drugs [omapatrilat and the comparator, lisopril] were well tolerated . . . there was one case of angioedema with [lisopril] and none with [omapatrilat]," see id. (citing DX 156);

. another AHA abstract noting that in hypertension trials omapatrilat and lisopril were "similarly well tolerated," see id. (citing DX 161); and

. lastly, the deposition testimony of each of the speakers of the sixteen challenged statements in the First Class Period, each of whom have testified, in so many words, that they had every reason to believe that their statements were true or were opinions reasonably based on facts, see id. at PP85-118.

While this list is not exhaustive of the evidence cited by Defendants to support their position that all of the challenged statements were objectively true or were reasonably based upon facts, it is representative. It is also important to note that [HN32] the belief of individual speakers in the truth of their statements [*83] is irrelevant if those statements were "adopted or endorsed" by one of the defendants and that defendant exhibited conscious misbehavior or recklessness in its endorsement or adoption. See *In re Honeywell Int'l Secs. Litig., 182 F. Supp. 2d 414, 428 (D.N.J. 2002)*. Whether or not the statements of doctors in the first class period were indeed endorsed or adopted by BMS is discussed in detail below, for now, it suffices to say that the deposition testimony demonstrating the speakers belief in their own veracity can only take Defendants so far -- if Defendants knew or were reckless in not knowing that these statements were false or misleading BMS can be liable for fraud in connection with the statements.

Another preliminary issue, before getting to Plaintiff's evidence, is that a good portion of Defendants' evidence is the subject of Plaintiff's Motion to Strike Material from the Summary Judgment Record, filed on May 13, 2005. But even if all the challenged evidence were admissible, evidence that the challenged statements were objectively true or reasonably based on facts, must be considered both in the context of contemporaneous evidence to the contrary and with regard [*84] to its rele-

vance, insofar as Plaintiff alleges an actionable omission. Thus, it makes sense to consider Plaintiff's evidence before deciding the Motion to Strike.

Plaintiff's Evidence: In its Opposition to Defendant's Motion, Plaintiff offers evidence tending to show, that whatever optimistic conclusions could have been drawn when looking at the early clinical trials in isolation, (1) individuals at BMS were aware, concerned and vocal about the incidence and severity of angioedema (both generally and in the "037" study in particular); and (2) the results of those trials could have and should have been compared to databases cataloging the side effect profile of other ACE inhibitors. These databases, Plaintiff argues and offers evidence to prove, establish clearly that Vanlev was not "equally well tolerated."

First, Plaintiff has produced evidence suggesting that as early as December 4, 1998 individuals at BMS knew that the side effect profile of Vanlev in comparison to currently marketed ACE inhibitors was going to be a critical issue with respect to FDA approval. For example, in an e-mail written shortly after the second tracheotomy during the clinical trials, on or about December 4, 1998, a [*85] senior marketing employee, Tony Coniglio, wrote to colleagues: "We will still have strong efficacy data . . . but a profile of side effects that is much worse than ARBs (and ARB/diuretic combos), and not even as good as ACEIs. Norvasc's success has been not only efficacy but creating a perception of greater tolerability than other CCBs" PX 220:OMA0651637.

Second, Plaintiff has produced evidence tending to show that in the Spring of 1999, before any of the challenged statements, Kathleen Moulton of BMS was tasked with collecting the reports of investigator identified angioedema in the Vanlev clinical trials -- and these reports raised flags. PX 215:OMA1908263 (internal e-mail from Moulton to Paul Chang, Elliott Levy and Richard Reeves of Vanlev's clinical and safety teams, among others). Moulton's e-mail, dated April 26, 1999, states that "as of today, investigator identified angioedema has been reported in 40 subjects (36 of these subjects were in the [hypertension] program). This includes only [adverse events] coded as angioedema and is based on entered data. Exposure to [Vanlev] is estimated to be 6476 subjects (thus, 0.62%)." Id.

The handwriting of Joanna Whyte, a junior [*86] epidemiologist in BMS's Outcomes Research department, appears on the printed copy of this e-mail. See Id. Wyte notes that the angioedema rate "could be higher." PX 215. When asked at deposition what she meant by this, Wyte testified: "I don't know why I wrote this." Wyte Dep., PX 40 159:5. But a jury could reasonably infer that Wyte thought the angioedema rates could have been higher because a number of angioedema events were not coded properly: The Moulton e-mail explains that rates discussed only include "[adverse events] coded as angioedema and is based on entered data," and another e-mail reply to Moulton, from Reeves, states that in these "updated #'s . . . AEs [adverse events that are] coded otherwise, eg "facial edema," etc are not included." PX 215: OMA1908263.

Third, in a handwritten note produced in connection with the Moulton e-mail, Whyte noted that BMS "want[s] to develop [a] position paper on angioedema. How do we join the two (angioedema and [Vanlev]) without saying 'hey this is a problem.'" PX 215:OMA1908269. Whyte further noted that BMS "need[s] to look [at] all cases that we think may be angioedema (i.e., coded as angioedema or other)." Id. [*87] Whyte concludes by setting forth a list of needed items, including: "inside & outside database work up," "a work plan of how [Vanlev] is being handled;" "physician consulting visit (will need to be handled carefully);" and "new database study done inside (internal-captopril, monopril for ISS review)." Id.

Fourth, Wyte's investigations were discussed at an "Angioedema meeting and teleconference" on May 5, 1999, which was attended principally by marketing staff, but also included staff from clinical safety and epidemiology, to discuss the increased incidence of angioedema with omapatrilat. PX 174:OMAP0091644.0001. One slide prepared for the meeting stated, "We want to find a lower incidence in patients on Omapatrilat . . . than on other ACE Inhibitors." PX 58:OMA1910189. By the spring of 1999, the evidence suggests, the Outcomes Research Department had considered the possibility of obtaining data from large external databases, like Henry Ford, to permit some meaningful comparisons of angioedema experiences between Vanlev and ACE inhibitors. PX 58:OMA1910186.

To this end, on May 5, 1999, five specific suggestions for a continuing investigation of the incidence of angioedema were [*88] drafted, to be discussed with BMS's "CV [Clinical] and Global Marketing" groups: These were (1) preparation of a backgrounder report on angioedema *in general;* (2) in Phase II Vanlev trials *specifically* (to be completed by Mary Bethala-Sithya and Richard Reeves); (3) consultation with outside physicians; (4) an internal analysis of angioedema rates in a healthcare database; and (5) review of data on BMS ACE inhibitors captopril and monopril. PX 174:OMAP0091644.0001 (emphasis added). Each of these options was to be discussed with BMS's Clinical and Global Marketing groups, and it was noted that "Safety, CV [clinical] and OR [outcomes research] [would] be needed to implement an effective strategy." Id. Whyte's notes indicate that her that her literature re-

view should not integrate information from the Vanlev database. PX 213:OMA1910192.

Upon completion of her literature review, Whyte determined that the risk of ACE inhibitor induced angioedema was frequently recognized as 0.1-0.2%, but proposed that rates ranged from 0.1 - 1.0%, citing four studies. Id. This finding was very positive for Vanlev.

However, with respect to one of these four studies, relating to [*89] the angioedema rate with Captopril, which Whyte reported as 1%, Plaintiff asserts, and the Court agrees, that a reasonable jury could find that Whyte made a simple transcription error. See Pl.'s 56.1 P86. Indeed, Captopril is a BMS product for which BMS had access to the developmental database and NDA, and for which Whyte's own Table III indicates an Angioedema rate of only 0.1%. See PX 183:OMAP0046799.0016; PX 211 (similar chart with same data on Captopril). The Physician Desk Reference also states that Captopril is associated with a low incidence of angioedema: 0.1% or 1 in 1,000 patients. DX 52:1960. Once again, Kathleen Moulton's e-mail concerning the angioedema rate estimated from the Vanlev trial was around 0.62%. PX 215:OMA1908263.

Fifth, although he could not recall the timing, Dr. Robert Wolf of BMS testified that in 1999 he reviewed some antihypertensive drug "summary bases of approval" (SBAs) in order to gain an understanding of the angioedema experience. DX 49 48:22-49:16. He did not identify any reports of intubation directly linked to angioedema and testified that he requested the SBAs from BMS's regulatory department. Id. The inference that BMS had opportunities [*90] to undertake a more complete review of angioedema as seen in the SBAs of ACE inhibitors can be inferred from Dr. Wolf's testimony and from the testimony of Dr. Laurie Smaldone, who at the time of the Vanlev trials was BMS's Senior Vice-President of Worldwide Regulatory Affairs. DX 29 (Smaldone Dep) at 11:7-14; 151:23-152:9 ("I would not be surprised if an SBA review was undertaken [in 1999] because that would be part of the broader literature review.").

A number of the aforementioned facts (and inferences drawn therefrom) are contested by Defendants. Of particular importance is Defendants position that the first time anyone at BMS had ever heard about the comparison of outside databases to Vanlev data was at the company's February 11, 2000 meeting with the FDA:

> . . . The fact they say we should have disclosed [is] that the databases that the FDA had[,] showed a better safety profile for ACE inhibitors than it did for Vanlev. When did we first hear anything like that? February 11, 2000. There's nothing in the record that suggested we had access to the FDA databases before that, nor could we. They are confidential to the agency and drug companies do not have access to [*91] those databases. What we had was access to public databases of drugs in the marketplace which showed that people had died from ACE inhibitors. And no one had died during the Vanlev trials. That's all we had when we said the safety profiles were comparable. . . . After they told us that they had a database internally that had a difference between ACE and Vanlev . . . we made two statements, the two statements I mentioned to you before, on March 10 and March 11, and neither one of them was published to the marketplace.

Trans. at 91:4-21.

Ultimately, regardless of whether every public, private and FDA database was accessible before the February 11, 2000 meeting with the FDA, it would certainly be reasonable for a jury to assume, based on the above detailed evidence, that at least some databases -- *e.g.*, BMS's internal data on captopril and monopril and the SBAs for other ACE inhibitors -- were available for an intensive comparison to the data in the Vanlev database. Moreover, after the February 11, 2000 meeting, BMS senior-management did task one of its epidemiologists, Dr. David Lilienfeld, with obtaining and analyzing data from large databases in order to compare Vanlev [*92] with other ACE inhibitors, with respect to both the incidence of all angioedema and the incidence of life-threatening angioedema -- this time, in preparation for the FDA advisory committee meeting in May 2000. PX 330; 30 56:3-25; PX 175; 176; 177. Databases consulted by Lilienfeld, on the rates of angioedema and intubation in ACE-inhibitor-treated patients, included publicly (and privately) accessible sources and databases such as SBAs, Henry Ford and MediCal. PX 330; 30 56:3-25; PX 175; 176; 177.

From all of the above facts, it could be inferred that such an intensive comparison could have been undertaken as early as the Spring of 1999, when individuals at BMS were aware of the possible problem with angioedema. Among other things, Dr. Lilienfeld's comparison revealed that (1) in a MediCal database of 201, 188 patients taking ACE inhibitors, 1 intubation occurred, for a rate of 0.00005 events per subject; (2) in the Brown database of 27,834 ACE inhibitor patients, 4 intubations

occurred, for a rate of 0.00014 events per subject; and (3) in a Henry Ford database of 17,655 ACE inhibitor patients, 2 intubations occurred, for a rate of 0.00011 events per subject. PX 176: OMAP0020553.0003. [*93] The Vanlev database (including 20mg and 10mg regimens) showed that among 6662 patients 4 intubations occurred, for a comparatively higher rate of .0006. Id.

As further proof that Defendants knew or were reckless in not knowing that the challenged statements were false or misleading, Plaintiff has submitted evidence that by December 1999 it was clear to a number of individuals at BMS that African American women taking Vanlev experienced a greater than expected incidence of angioedema. This evidence is particularly compelling because at least one piece of evidence cited by Defendants, the Vanlev Integrated Summary of Safety ("ISS"), cited to show that the challenged statements were grounded in fact, includes discussion of how Vanlev would be a particularly *good* treatment for sub-populations including, among others, African Americans. Defs.' 56.1 P163 (citing DX 282). The "Summary and Conclusions" section of the ISS, besides stating that "Omapatrilat was safe and well tolerated," also states that "Omapatrilat is effective regardless of age, race, or gender," and that "Omapatrilat is effective in difficult to treat populations including blacks . . .." DX 282:163.

While the [*94] Court is mindful that effectiveness and safety are different measures that do not always overlap, it appears that a reasonable jury could find that an especially frequent and severe side effect among African American patients, directly contradicts the idea that the drug would be a particularly effective treatment for that group. To this extent, insofar as Defendants had serious concerns about the incidence and severity of angioedema in blacks, Defendants' evidence of reliance on a document that touts the good prospects of the drug for treating blacks is of dubious worth.

Plaintiff's evidence regarding Defendants' knowledge of "037" study is extensive. It appears that even before the ISS was drafted, individuals at BMS were very concerned about angioedema in African Americans. For example, in an e-mail dated December 8, 1998, before any of the challenged statements were made, in which Richard Reeves and Dan MacNeil discussed the second tracheotomy in the clinical trials, Reeves noted that "this guy appears to have had life-threatening angioedema . . . one other case was this bad." PX 128. In response, MacNeil noted that:

> At present, there are 23 other serious and non-serious [*95] cases which have been entered into the Clintrial [Vanlev] database. Assuming a 4000 patient exposure to date, the incidence remains well below 1% as stated in the brochure. Of note, 11 of the 23 are black which is consistent with what has been suggested in the literature. More striking, is that 9 of these 11 are females. *Black women may have a greater risk of developing angioedema than others. We will have to look at this as our data is unblinded.*

Id. (emphasis added). Then, in an e-mail dated July 14, 1999, MacNeil reiterated to Reeves that "I continue to believe that our final data will show a substantially greater risk of angioedema for black females." PX 130. In October 1999, Defendants had completed data analysis from the head-to-head trial comparing Vanlev with the ACE inhibitor lisinopril in African-American patients -- this was the "037" study. DX 279; 155; 180; 283. In this trial, 12 of 301 Vanlev patients had suffered angioedema and 1 of 295 lisinopril patients. DX 279.

In addition, Michael Mitnick's notes from a meeting held on September 13, 1999 indicate that senior level clinical and regulatory staff discussed the "037" results as well as the incidence [*96] of intubation in the overall clinical trials and how it should be reported to FDA -- all before any of the challenged statements were made. PX 427. Among the attendees were BMS senior management, Drs. Hubert Pouleur, Sol Rajfer and Laurie Smaldone. Id. The notes indicate the number of intubations in the Vanlev clinical trials to date, broken down by race, as well as the incidence of angioedema seen in the clinical trials to date. Id. The notes also indicate that following a discussion of the incidence and severity of angioedema in the Vanlev clinical trials, and Bodnar's acknowledgment that the FDA would conduct a risk/benefit analysis, Joel Lasker, BMS's in-house counsel, directed the 17 participants to "be careful in all writings." Id.

One of the earliest draft "safety updates" intended for submission to the FDA in support of BMS's request for priority review, dated September 20, 1999, is headed "EVENT: Angioedema in Black Women." PX 125:OMA0974087. This draft offers an analysis of the rate of angioedema observed in 4200 omapatrilat-treated patients in short-term double-blind hypertension studies and one open-label trial. Id. In these trials, according to the draft, [*97] 4.27% of African-American women exposed to Vanlev suffered angioedema, as compared with 1.67% of African-American men, 0.63% of all other women, 0.63% of white men and 0.52% of men of other races. Id. The draft states that "Angioedema requiring intubation or tracheotomy was reported in only 4 subjects." Id. The draft also communicates that the rate of

angioedema in African-American women on Vanlev was in excess of what was expected:

> Published reports indicate that angioedema associated with ACE-inhibitors occurs with an incidence of <1% in the Caucasian population but may be 3-fold higher in Black Americans . . .. However, the rate seen in black women on [Vanlev] (4.27%) was almost 7-fold greater than that reported in Caucasians treated with the study drug. Reasons for this difference are unclear and further analysis of these findings to identify other risk factors for angioedema in this subset of the study population are ongoing.

PX 125. In contrast, a later draft dated September 24, 1999, cites tobacco use a potentially greater risk factor for angioedema than race alone. PA 124:OMA1630950.

The September 20, 1999 draft also states that "in contrast to the [*98] hypertension studies, only 2 (0.2%) cases of angioedema have been reported to date from the more than 1000 subjects (including about 160 black subjects) exposed to omapatrilat in completed short and long-term double-blind heart failure trials." Id. at OMA0974087. Drafts circulated later on September 20 and September 23, 1999 aggregated the patient numbers in the hypertension and heart failure trials. PX 456. Among this aggregated pool, African-American Vanlev patients were at a 5-times greater risk for angioedema, as opposed to the 7-fold greater risk observed in the hypertension population separately. Id.

Ultimately, in BMS's final submissions to the FDA, investigators reported that "four subjects have had airway compromise requiring intervention . . .." See DX 279; PX 172; PX 181; PX 124: OMA1630950. The words "intubation" and "tracheotomy" were not used. Id. Expert testimony is offered by both parties on the question of whether "airway compromise" is a term that would tend to understate the severity of the angioedema caused by Vanlev. The admissibility of this evidence is the subject of cross-motions to exclude not decided here.

Even without considering expert [*99] evidence, however, it is clear that the mere change in terminology from one draft to the next could be the source of a reasonable inference that BMS was attempting to downplay, to the public, the incidence and severity of angioedema. The same inference could be drawn from the decision to aggregate the angioedema statistics from the heart failure and hypertension trials. Defendants argue that this inference is only possible in hindsight - after the FDA decided to look at look at hypertension and heart failure separately. Reply at 9. Indeed, if there were no evidence that prior drafts presented these statistics in disaggregated form, Defendants would have a valid point -- but here, it was well before the FDA decided to look at hypertension separately, that individuals at BMS considered and rejected publicly presenting the disaggregated data.

The previous several pages catalog the parties' evidence concerning what Defendants knew or were potentially reckless in not knowing about the incidence and severity of angioedema as seen in the clinical trials. The next section applies the relevant law to these facts to determine whether Defendants can be found liable for the challenged statements. [*100]

III.C.2.c. Statements in the First Class Period Directly Attributable to Defendants

The first challenged statement unquestionably attributable to at least one Defendant (statement number five) was made by Peter Ringrose, then Chief Scientific Officer of BMS, following the AHA seminar, on or about November 29, 1999, during an interview with "The Financial Times." See DX 41 150-51; PX 246. Specifically, Ringrose stated that: "If you asked a cardiologist what the ideal drug would do, Vanlev pretty much ticks all the boxes. . . . We have three blockbusters at the moment, but we should have three more in Plavix (an antithrombotic), Avandia (for diabetes) and Vanlev." Id. As discussed above, the statement about what "should" happen with Vanlev is forward-looking in nature. See, supra, § III.C.1.

[HN33] A forward-looking statement is not actionable at all if it is nothing more than a "vague expression of corporate optimism [or] expectations about a company's prospects," because such statements are not relied on by reasonable investors. *In re Aetna Inc. Securities Litigation, 34 F. Supp. 2d 935, 945 (E.D. Pa. 1999)* (citing *Lasker v. New York State Elec. & Gas Corp., 85 F.3d 55, 57-58 (2d Cir. 1996)).* [*101] This determination can be made before the summary judgment stage because forward-looking language is evident on the face of the statement. Indeed, in this Court's 2004 Opinion it was settled, that while a statement of this ilk is indeed forward-looking, it is not of the class of statements that is per se immaterial, thus, the statement was not dismissed from the Complaint as a matter of law. The 2004 Opinion explained that

> statements, [which] to varying degrees, link Vanlev to the status of "blockbuster" or "best-in-class" . . . given the allegations in the Complaint -- that Defendants had

> equated "blockbuster" with being a multi-billion dollar product . . ., that blockbuster appears to have a specific meaning in the industry, that Defendants knew with greater and greater certainty that Vanlev would never be a blockbuster . . ., and that Vanlev was thought of as the only reason to own BMS stock . . ., Plaintiff has adequately plead that the misrepresentation of Vanlev as a blockbuster is a material and actionable misrepresentation.

2004 Opinion at 71 (citing Judge Brown's Memorandum Opinion of March 9, 2001 at 23-24.). While the evidence may or may not support an [*102] inference that the statement was true or believed to be true when made, see discussion below, the Court's previous analysis that the statement is material to investors is unchanged in light of the evidence presented. See, supra, § § III.B.1, III.C.1.

It is also worth noting that most of the statements referring to the "blockbuster" potential of Vanlev were made in the Second Class Period. For these statements as well, Defendants' first line of defense -- that regardless of any safe-harbor, these forward-looking statements are immaterial -- remains, to the extent it was unpersuasive in the Court's 2004 Opinion, unpersuasive in light of the evidence available at summary judgment.

Still, statement number five, and other [HN34] forward-looking statements like it, may be protected by the PSLRA safe-harbor or the "bespeaks caution doctrine." The PSLRA contains a statutory safe harbor for forward-looking written or oral statements. Under that provision, an issuer is not liable for a forward-looking statement if it is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially [*103] from those in the forward-looking statement." *EP Medsystems, Inc. v. EchoCath, Inc., 235 F.3d 865, 872-873 (3d. Cir. 2000)* (citing *15 U.S.C.A. § 78u-5(c)(1)(A)(i) (West Supp.2000)*).

[HN35] The statutory safe harbor is available for oral forward-looking statements under certain conditions. Id. "Under the Reform Act, an issuer is not liable for any oral forward-looking statements if (1) the issuer informs the audience that the statement is forward-looking and that actual results may differ materially from the predictions; (2) the issuer orally directs the audience to other "readily available" written documents that contain the additional information about important factors relating to the forward-looking statement; and (3) the identified documents set forth satisfactory cautionary statements." Id. (citing *15 U.S.C.A. § 78u-5(c)(2)(B) (West Supp.2000)*).

[HN36] The safe harbor does not apply if the statement was made with "actual knowledge" that the statement was false or misleading. *Advanta, 180 F.3d at 535 (3d Cir. 1999)* (citing *§ 78u-5(c)(1)(B)(i)*). A forward-looking statement carries various testable [*104] factual assertions: the speaker genuinely holds her opinion; there exists a reasonable basis for her opinion; the speaker knows of no uncontested facts that contradict the opinion. Hence, if one of these implicit assertions is provably false, a forward-looking statement can be "false."

[HN37] The PSLRA did not supercede yet another layer of protection for forward-looking statements, the "bespeaks caution doctrine." See *In re Adams Golf, Inc. Secs. Litig., 381 F.3d 267, 278-79 (3d Cir. 2004)*. Statements "not identified as forward-looking as required by the safe harbor provision," may still be protected under the bespeaks caution doctrine as adopted by the Third Circuit in *In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357 (3d Cir. 1993). EP Medsystems, 235 F.3d 865, 873 (3d Cir. 2000)*. "Under this doctrine, 'cautionary language, if sufficient, renders the alleged omissions or misrepresentations immaterial as a matter of law.'" Id. "'Bespeaks caution' . . . is essentially shorthand for the well-established principle that a statement or omission must be considered in context, so that accompanying statements may render it immaterial as [*105] a matter of law." Id. But not just any cautionary language will trigger application of the bespeaks caution doctrine. Instead, the Third Circuit requires that disclaimers

> relate directly to that on which investors claim to have relied. . . . [A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions . . . which the plaintiffs challenge.

Id. (citations omitted).

Finally, [HN38] as with the PSLRA safe harbor, the bespeaks caution doctrine will not immunize forward-looking statements that are made with actual knowledge of their falsity at the time they are made. See Id. (citing, with approval, *Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 (1st Cir. 1996)*, which explained that a statement may contain "both a forward-looking aspect and an aspect that encompasses a representation of present fact," and "to the extent that plaintiffs allege that the . . . statement encompasses the latter representation of

present fact, [*106] and that such a representation was false or misleading when made, the surrounding cautionary language could not have rendered the statement immaterial as a matter of law.").

Defendants argue that because statement number five is "cautionary" on its face -- insofar as it says that Vanlev "*pretty much* ticks all the boxes" and it "*should* be a blockbuster"-- both the PSLRA safe harbor and the bespeaks caution doctrine shelter this statement from liability. Defs.' 56.1. P401-02; Defs.' Mem. at 19-20; Reply at 16-18. This argument is unpersuasive. The problem is that Defendants rely on the word "should" for dual, but incompatible, purposes. It cannot be the case that the very same words that render a statement "forward-looking"-- *e.g.*, "may," "might," "will," and "should"-- can do double duty as "cautionary language" under the bespeaks caution doctrine or the PSLRA. That would put *every* forward-looking statement into one or both of the safe-harbors and the "cautionary language" requirement would be a makeweight. Notwithstanding that issue, here, it can hardly be argued that the word "should" is "substantive and tailored to the specific future projections." *EP Medsystems, 235 F.3d at 873.* [*107]

Thus, neither the PSLRA nor the bespeaks caution doctrine apply to statement number five. As such, Plaintiff can prove scienter through evidence of conscious misbehavior or recklessness: [HN39] "Opinions, predictions and other forward-looking statements are not per se inactionable under the securities laws. Rather, such statements of 'soft information' may be actionable misrepresentations if the speaker does not genuinely *and reasonably* believe them." *In re Donald J. Trump Casino Securities Litigation-Taj Mahal Litigation, 7 F.3d 357, 368-369 (3d Cir. 1993)* (emphasis added).

Nevertheless, with respect to statement number five, Plaintiff has failed to show recklessness -- and this is true even if Plaintiff's Motion to Strike were granted. The problem is that none of Plaintiff's evidence of recklessness is sufficiently related to the content of the statement. Recall the first part of the statement -- "If you asked a cardiologist what the ideal drug would do, Vanlev pretty much ticks all the boxes. . . ." This part of the statement does not mention side effects; the results of the clinical trials; the comparison of Vanlev to currently marketed ACE inhibitors; or what [*108] types of cardiologists are being asked about their "ideal drug." As a result, the statement leaves open the possibility that the incidence and severity of angioedema is the one box that Vanlev does not "tick." The evidence set forth above is insufficient to prove that Ringrose could not have genuinely and reasonably believed that Vanlev exhibited the remaining characteristics of the "ideal drug" for cardiologists. Essentially, the statement is just too general for Plaintiff to specify any evidence that contradicts it.

The second part of the statement --"We have three blockbusters at the moment, but we should have three more in Plavix (an antithrombotic), Avandia (for diabetes) and VANLEV."-- is also unprotected under the bespeaks caution doctrine and/or the PSLRA. But here too, Plaintiff has failed to adduce evidence sufficient to prove recklessness. Putting aside the possibilities for Vanlev as a hypertension treatment, this statement was made before anyone at BMS had serious reasons to doubt the promise of Vanlev as a potential treatment for heart failure. This remains true even if Plaintiff's Motion to Strike were granted. Moreover, unlike some other challenged statements in [*109] the first class period, which are allegedly misleading because they incompletely assess the side-effect profile of Vanlev, or the clinical trials (see statements one, two, three, four, six, seven, eight, ten and eleven), the portion of statement number five referring to Vanlev's "blockbuster" potential is uncontradicted by any of the evidence. Plaintiff has, thus, failed to adduce sufficient evidence of scienter. **For this reason, Defendants' Motion will be granted with respect to statement number five.**

Next, on December 20, 1999 and again on January 10, 2000, before the February 11, 2000 meeting with the FDA, BMS issued two substantially similar a press releases, each announcing that it had filed an NDA with the FDA seeking approval for Vanlev. DX 241; PX 247. In these press releases, BMS stated that "In placebo-controlled clinical trials, the most commonly reported side-effects were headache (more common in the placebo group), dizziness, upper respiratory [tract] infection and cough." DX 241; PX 247 (statements seven and eight). Statements seven and eight are not forward-looking in nature and Plaintiff does not challenge the objective truth of the statements. Rather, [*110] Plaintiff alleges that failure to mention the company's concern with angioedema made the statements materially misleading. See Compl. PP66. As discussed above, § III.B.3, even objectively true statements can be actionable if Defendants omitted information rendering the statement false or misleading, or if Defendants failed to update forward-looking statements that later became inaccurate.

Here, ample evidence presented would permit the inference that, at the time of this statement, the company had serious concerns about the incidence and severity of angioedema with Vanlev, especially relative ACE inhibitors marketed at the time and especially among African Americans. See, supra, § III.C.2.b. Discussion of the "most commonly reported side effects" without mentioning a side effect that was the subject of substantial attention and concern at BMS is a misleading half-truth. Because a jury could infer that control persons at the com-

pany knew or were reckless in not knowing that statements seven and eight were misleading, **Defendants' Motion with regard to statements seven and eight will be denied.**

Next, as mentioned above, on February 11, 2000 officers of BMS met with the [*111] FDA. At this meeting, the FDA expressed concerns about whether "angioedema associated with omapatrilat is of a greater incidence or severity than that associated with the other ACE inhibitors," and noted that in "the head-to-head comparator study against lisinopril in black patients . . . the incidence of angioedema was 10-fold greater on omapatrilat than on lisinopril." DX 56:OMA0004558; PX 55:OMAP0046092.0002. The FDA did not indicate that these concerns would prohibit approval of Vanlev. DX 11:28; DX 56; DX 57; DX 32: 16-136:2. But Plaintiff argues, and the Court agrees, that after this meeting, a number of high level managers at BMS had actual notice of the FDA's serious concerns about the side effect profile of Vanlev compared to other ACE inhibitors. Only three of the eleven statements alleged to have been made in the first class period were made after this meeting. These three statements are discussed below.

Only one of the three statements made after the February 11, 2000 meeting, statement number nine, was made directly by BMS (as opposed to an outside physician). On January 13, 2000, BMS announced that Canada had granted priority review for Vanlev. DX 74. In this press release, [*112] BMS stated that priority review in Canada was granted only when, *inter alia,* "there is 'substantial clinical evidence that the drug provides significantly improved efficacy or significantly diminished risk over existing therapies . . . for a disease or condition that is not adequately managed by a drug marketed in Canada." Id. Plaintiff does not challenge the objective truth of the statement. See DX 296:2; Compl. P69. The statement is only challenged to the extent that it allegedly omits material information. Id. Specifically, Plaintiff argues that "this statement was false and misleading since Vanlev did not provide significantly improved efficacy or diminish risk over existing therapies for a disease that was not adequately controlled. Indeed, by failing to mention the incidence and severity of angioedema." Pl.'s 56.1. P277.

The Court is mindful of the fact that after the February 11, 2000 meeting with the FDA, BMS could not credibly state that Vanlev promised "significantly improved efficacy or significantly diminished risk over existing therapies," without mentioning the FDA's concern with angioedema. Statement number nine, however, doesn't speak to the qualities [*113] of Vanlev at all: It doesn't speak about the results of the clinical trials of Vanlev or the side-effect profile of Vanlev. Statement number nine only states Canada's policy. Moreover, the only evidence Plaintiff cites in connection with this statement, see Pl.'s. 56.1 P277, is a PaineWebber document indicating that analysts raised their estimates of BMS earnings and Vanlev sales estimates based on the FDA's grant of priority review. PX401:OMA0043271. This document makes no mention of the Candian approval -- and Plaintiff has no evidence to back up the assertion that statement nine was made misleading by omitted information. Based on this record, a reasonable jury could not find that statement number nine is false on its face or that it omits material information. **For this reason, with respect to statement number nine, Defendants' Motion will be granted.**

The last statements made in the First Class Period, after the February 11, 2000 meeting with the FDA, were made by Drs. Ferdinand and Dahlof on March 11 and 12, 2000, respectively. These are discussed in the next section, which considers the potential liability of Defendants for numerous statements made by physicians not [*114] employed by BMS including Drs. Ferdinand, Dahlof, Weber and Black.

III.C.2.d. Statements by Weber, Black, Ferdinand and Dahlof

The first challenged statement by a non-BMS physician was made by Dr. Weber, on November 8, 1999, in an oral presentation accompanied by slides at the AHA Symposium. When answering questions posed after his presentation Weber stated, "as far as the side effect profile is concerned, right now as yet I have not seen any evidence that this drug [Vanlev] differs from traditional ACE inhibitors in its side effect profile." PX 450:OMA1787535-36 (challenged statement number one).

Plaintiff argues that statement number one is actionable as an affirmative misstatement of material fact or, alternatively, that is was rendered misleading by the omission of material facts. Plt. Fcts P171; Compl. PP54-55. Defendants argue, initially, that the statement is true. Defs.' Mem. at 17; Reply at 15. Indeed, with respect to statement number one, Plaintiff has failed to adduce evidence that Weber's assertion of what he had "seen," and what he concluded from that -- speaking only for himself -- omitted anything that rendered the statement false or misleading. Nor, has [*115] Plaintiff cited any evidence that any Defendant knew or was reckless in not knowing that the statement was false or misleading. Plaintiff offers some evidence which could suggest that Dr. Weber knew that there had been two intubations and two tracheotomies at the time of the AHA conference. DX 48 45:3-20; DX 41 144.9-145:18; DX 46 54:23-56:16. But this evidence is insufficient to permit the inference that Weber had seen evidence (perhaps known to BMS) that

this incidence differed from clinical data on traditional ACE inhibitors.

To the contrary, and irrefuted by Plaintiff, is the sworn declaration of Dr. Weber indicating that his statement of what he had seen to date was true at the time he made it and that, even if it were not objectively true, it was his subjective analysis that the data regarding ACE inhibitors was no different than Vanlev. DX 10: PP11-21. Plaintiff has disputed P15 of the Weber Declaration insofar as it "offers speculation and unsupported conclusions as to whether Defendants intended to mislead anyone regarding Vanlev, and as to what Defendants knew and believed . . . ." Plaintiff's Memorandum of Law in Support of Motion to Strike Material from the Summary Judgment [*116] Record ("Pl.'s Mem. to Strike") at 6. The reasoning that "Dr. Weber is not competent to testify as to what others intended or believed, or as to what others were or were not aware of," however, does not apply to Weber's declaration of his own personal knowledge. Thus, a jury could not reasonably conclude that Defendants knew or were reckless in not knowing that Dr. Weber had in fact seen evidence to the contrary. **For all of these reasons, Defendants Motion will be granted with respect to statement number one.**

In addition to statement number one, in connection with an AHA-symposium-related press conference, doctors Black and Weber made the following representations (challenged statements two, three and four):

. As reported in a Bloomberg article on November 8, 1999, Dr. Black stated the following about the Phase III data: "These are very impressive results from a large group of patients and the data indicate Vanlev may be "the best choice for doctors." PX 240 (challenged statement number two).
. In a November 8, 1999 PR Newswire press release, Dr. Black stated that "the overwhelmingly positive clinical data presented here suggest that omapatrilat is a superior treatment [*117] in a broad range of patients with hypertension, as compared with several currently available agents for this disease . . . . These collective data are the most compelling we've seen about any new cardiovascular agent in the past 15 years." PX 241 (challenged statement number three)
. In a November 8, 1999 PR Newswire press release Dr. Weber and the Brookdale University Hospital and Medical Center reported, "To date, omapatrilat has been studied in more than 6,500 patients and has been generally well-tolerated, with a safety profile comparable to several leading hypertension therapies." PX 241 (challenged statement number four).

In addition, after the AHA seminar, Dr. Weber represented, in an article entitled, "Emerging Treatments for Hypertension: Potential Role for Vasopeptidase Inhibition," published in the November 1999 Supplement Issue of the American Journal of Hypertension, Volume 12, Number 11, Part 2, that "Omapatrilat was well tolerated, and discontinuation rates due to adverse events were similar in the omapatrilat, lisinopril and placebo groups." PX 245:OMA1124654. (challenged statement number six).

The first issue with regard to these five statements is whether [*118] they can be attributed to any or all of the Defendants -- if there is no evidence supporting attribution they must be dismissed. See Defs.' Mem. at 21; Reply at 19-20. [HN40] Where a defendant has adopted or endorsed a third-party's statement, a plaintiff need only show that the defendant -- not the third party -- acted with scienter. See *In re Honeywell Int'l Secs. Litig., 182 F. Supp. 2d 414, 428 (D.N.J. 2002)* (finding that Defendants acted with scienter in providing analysts with false statements that were then published in analysts' reports).

As Judge Brown recognized in his 2001 Opinion at 22, [HN41] to hold a defendant liable for the misstatements made by non-employee third parties, a plaintiff must prove that the defendant either "(1) intentionally fostered a mistaken belief concerning a material fact that was incorporated into [statements] . . .; or (2) adopted or placed [its] imprimatur" on the third party's statements. See also *Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)*. Indeed, "although a company is not generally responsible for the accuracy of statements made by [third parties], a company may adopt or endorse a [statement] causing [*119] the [statement] to be attributed to the company." *In re DSP Group Sec. Litig., 1997 U.S. Dist. LEXIS 11942, No. C 95-4023-CAL, 1997 WL 678151, at *8 (N.D. Cal. Mar. 5, 1997)*.

The theory of liability is "that a company may so involve itself in the preparation of reports and projections by outsiders as to assume a duty to correct material errors in those projections." *Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 163 (2d Cir. 1980)*. "This may occur when officials of the company have, by their activity, made an implied representation that the information they have reviewed is true or at least in accordance with the company's views." Id. In Elkind, the defendant corporation reviewed and corrected analysts' earnings forecasts before they were published. Id. Nonetheless, the Second Circuit refused to impute the forecasts to the defendant because the defendant never directly commented on the accuracy of the forecasts or suggested that the forecasts were in line with its own internal projections. Id. The company's failure to comment on the forecasts was not an implied representation that the forecasts were accurate because the defendant had a corporate policy of not [*120] commenting on forecasts. *Id. at 163*.

[HN42] The Third Circuit "[has] no problem with the 'adopt or endorse' test [because] to say that one is 'comfortable' with an analyst's projection is to say that one adopts and endorses it as reasonable." *In re Burlington Coat Factory, 114 F.3d 1410, 1428-29 (3d Cir. 1997)*. "When a high-ranking corporate officer explicitly expresses agreement with an outside forecast, that is close, if not the same, to the officer's making the forecast." Id. There is "no reason why adopting an analyst's forecast by reference should insulate an officer from liability where making the same forecast would not." Id.

In this case, Judge Brown has already held that allegations that Drs. Weber and Black were BMS's "paid consultants," who made misrepresentations at medical symposiums via presentation materials that BMS "reviewed and approved," were sufficient to show that BMS adopted or endorsed these doctors' public misstatements. See 2001 Opinion at 22. Consistent with Judge Brown's opinion, it is further clear, that facts showing that Black and Weber were paid consultants, standing alone, without further evidence that BMS [*121] "reviewed and approved" the challenged statements, are insufficient for a jury to attribute the statements to BMS. See *J/H Real Estate Inc. v. Abramson, 901 F. Supp. 952, 958 (E.D. Pa. 1995)* (citing *Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 163 (2d Cir. 1980)* and *Stack v. Lobo, 903 F. Supp. 1361, 1370 (N.D. Cal. 1995)*.

In order to establish "sufficient entanglement" a plaintiff must identify a specific analyst statement or forecast and the company insider who adopted the statement or forecast; point to the specific interaction between the insider and analyst that gave rise to the entanglement; and allege that the insider provided misleading information to the analyst, that appeared in its publication. Id. The question then, is whether Plaintiff can adduce sufficient evidence to support its allegations that BMS "reviewed and approved" Black and Weber's statements.

Defendants cite several cases for the proposition that a "one-way flow of information," which they suggest occurred when "BMS might have reviewed and discussed with Drs. Weber and Black some of the material regarding Vanlev," falls short of establishing that the [*122] Defendants adopted or endorsed specific statements. Reply at 20 (citing e.g., *In re Syntex Corp. Sec. Litig., 95 F.3d 922, 934 (9th Cir. 1996)* (rejecting as a matter of law allegations not rising to the level of adoption and endorsement); also citing *In re Stratosphere Corp. Sec. Litig., 66 F. Supp. 2d 1182, 1200 (D. Nev. 1999)* (granting summary judgment in the absence of a showing of adoption or endorsement)). See also *In re Caere Corporate Sec. Litig., 837 F. Supp. 1054, 1059 (N.D. Cal.1993)* (adoption occurs when a defendant "sufficiently entangled himself with the analysts' forecasts . . [there are] sound reasons to construe the entanglement requirement strictly").

In Syntex, there was a one-way flow of information, but that did not rise to the level of "entanglement" of the defendant corporation with unreasonable analyst reports because "when . . . asked about the analysts' predictions related to future earnings per share, [the defendant corporation's CEO] stated, 'We don't forecast earnings,' and emphasized that such estimates should not be attributed to [the corporation]." *Syntex, 95 F.3d at 934.* [*123] Likewise, the Stratosphere defendants "never commented upon submitted draft reports, except to correct matters of public record . . . such conduct would, at most, constitute a one-way flow of public information." *Stratosphere, 66 F. Supp. 2d at 1200* (citation omitted).

Here, Plaintiff adduces far stronger evidence of adoption (with respect to most of the statements) than that present in *Syntex* or *Stratosphere*. The following evidence, taken together, would be sufficient for a jury to reasonably conclude that there was a two-way flow of information between BMS and Drs. Weber and Black, through which BMS adopted certain of the challenged statements:

. Defendants admit in their Amended Answer to the First Amended and Consolidated Class Action Complaint, that "the information and conclusions presented at the [AHA] symposium were reviewed by BMS before the presentations." PX 1 P48.

. Plaintiff has produced: (1) an email from Richard Reeves of BMS to Linda Giering of Applied Clinical Communications (an outside publications vendor working with BMS) and others at BMS requesting that Giering *draft* a slide about adverse events in the three studies that [*124] would be discussed by Dr. Black at the AHA conference, see PX 63; (2) an e-mail from Terry Stevens to Anthony Coniglio ("Coniglio"), Richard Reeves ("Reeves") and Paul Chang of BMS indicating that Coniglio *made changes* to Dr. Black's proposed AHA oral presentation and/or slides used at that presentation, see PX 64; and (3) an e-mail from Jill Errington of Applied Clinical Communications to Coniglio and James Powell of BMS, indicating that Errington was sending *"pending your approval"* the slides that Dr. Black intended to used for the Canadian Advisory Board Meeting, PX 68. These slides, attached to the Errington e-mail, included statements that "omapatrilat is well- tolerated" and "well-tolerated, comparable to currently available agents." Id. at OMA0650187, OMA0650192.

. Plaintiff has produced an email from BMS, through Linda Giering to Black dated September 22, 1999, in which Giering *outlined the objectives and content* for AHA and a KOL meeting in Miami in January. PX 66. Giering advised Black that she would *draft* his presenta-

tions for his review. Id. In spite of Black's declaration to the contrary, see DX 1 PP14-17, from this evidence a jury [*125] could reasonably infer that Black subsequently received draft slides and or content for his presentations.

. There is further evidence that BMS's Public Affairs department began planning for AHA in August 1999 and that the Department sought to "*prepare* spokespersons (internal and external)" and *prepare* press releases for BMS and third parties. See PX 60 (emphasis added). In a memorandum entitled "Vanlev Media Activity Report," dated November 7, 1999, Ami Knoefler and Sylvia Sharockman of BMS indicated that they had "conducted aggressive media outreach to top international and US reporters about the AHA meeting and expected Vanlev Phase III study news." PX 67:OMA1032300-OMA1032304. They also noted that they "are encouraged . . . by plans for two omapatrilat reporters to be briefed on the [Vanlev] study results early Monday by Dr. Weber and Dr. Black." The authors then list the numerous media interviews scheduled for Black and Weber and explain how BMS arranged for the interviews and provided the reporters with background information on Black and Weber. Id.

. Plaintiff has also produced a group of e-mails, dated October 4, 1999, circulated among various BMS employees, [*126] including one reply from Coniglio in which the following comments were made:

> We had a reasonably good discussion with Mike [Weber] and Henry [Black] this weekend regarding AHA. [Black] is no problem, Linda [Giering] will keep *working with him* for the intro . . . [Weber] is another issue. As we look at the data we are *asking him to present,* it is underwhelming. Also, *we need to think through how we present the safety/tolerability data* . . .. Finally, once *we get the presentation finalized,* we need to physically meet with [Weber], *review in detail, and conduct media training/Q&A* . . . please see if we can meet with [Weber] before AHA in NY . . .."

PX 57 (emphasis added).

All of this evidence is compelling, but this last exhibit is a particularly striking example of two-way communications -- review *and* revision -- by BMS, which would tend to show BMS's adoption of Weber and Black's statements at the AHA conference, and related events. Taken together, the evidence cited above would provide sufficient grounds from which a reasonable jury could infer that BMS adopted Weber and Black's statements at the AHA symposium, and those in press releases [*127] and press conferences in connection with that event. But this evidence does not apply to all of Weber and Black's challenged statements with equal weight.

Notably absent from Plaintiff's evidence, see Opp'n at 48-39, is any support for the allegation that BMS adopted or endorsed statement number six contained in Weber's article published in the November 1999 Supplement Issue of the American Journal of Hypertension. PX 245:OMA1124654. See *Shuster v. Symmetricon, Inc., Inc., 1997 U.S. Dist. LEXIS 14007, 1997 WL 269490, *7 (N.D. Cal. 1997)* ("A company is liable only if it engages in conduct from which it could reasonably be inferred that the company expressly or impliedly placed its imprimatur on the reports.") (citation omitted). As discussed above, it would be insufficient for Plaintiff to argue, without supporting evidence, that the article was published as a "service" for BMS pursuant to the company's alleged consultancy agreement with Weber -- and at any rate, no such supporting evidence has been offered. See Pl.'s 56.1 P162. Weber is not a Defendant in this case and BMS cannot be liable for a third-party statement which it did not adopt or endorse. **Thus, Defendants' motion will be granted** [*128] **with respect to statement number six.**

Returning to Black and Weber's other statements, for which adoption by BMS is provable, Plaintiff must still prove that the statements were adopted with scienter. To this end, § III.C.2.b, supra, detailed evidence that BMS employees at high levels had serious concerns about angioedema observed during early clinical trials of Vanlev. To reiterate briefly, by November 8, 1999, individuals at BMS had voiced concerns about the incidence and severity of angioedema in the early clinical trials; individuals had urged a comparison of the incidence of angioedema in Vanlev to the incidence in other comparable drugs as reported in available databases (internal and external) and in SBAs; and Vanlev's data regarding angioedema in African Americans was much worse than other ACE inhibitors. In that section it was explained, further, how this evidence could permit a reasonable, even strong, inference that Defendants knew or were reckless in not knowing the false or misleading nature of statements suggesting that "Vanlev had been shown to be effective, to be generally safe and well tolerated and to present a risk of angioedema similar to competing agents. [*129] " Statements two, three and four all discuss the results of the clinical trials without mentioning these concerns. A jury could reasonably find that the statements were adopted by BMS, and that BMS knew or should have known that they contained material and misleading omissions. **For these reasons, Defendants Motion will be denied with respect to statements two, three and four.**

This brings us to the challenged statements made by Drs. Ferdinand and Dahlof. After the February 11, 2000

meeting with the FDA, BMS sponsored a variety of events in connection with conferences organized by the American College of Cardiology ("ACC") and the Association of Black Cardiologists ("ABC") in Anaheim, California from March 10, 2000 to March 15, 2000. PX 329; 243; 453. These conferences involved Drs. Black, Keith Ferdinand and Bjorn Dahlof. Id. BMS's desire to spread the word on Vanlev at the ACC event is apparent:

> The "[ACC] meeting serves as the 2000 'launch pad' for the dissemination of new Vanlev data, hypertension awareness messages . . . ACC provides us with a major opportunity to reinforce the VANLEV pre-launch messages to key business and health reporters who are interested [*130] in learning more about the brand. . . .

PX 243:OMA1265206 (Vanlev Public Affairs Overview).

In a presentation entitled "Vasopeptidase Inhibition: From Bench to Bedside," PX 244, delivered at the Association of Black Cardiologists conference in Anaheim on March 11, 2000, Ferdinand presented a slide which stated that: "The safety and tolerability profile of omapatrilat compares favorably with placebo"; "The overall safety and tolerability profile of omapatrilat is comparable to amlodipine and lisinopril"; and that the "Incidence of angioedema [is] comparable with current ACE inhibitors." PX 244:OMAP0050280.0033 (challenged statement number ten).

Plaintiff cites the following evidence to support its contention that this statement was adopted by Defendants:

> . An e-mail from BMS marketing executive Anthony Coniglio ("Coniglio") to various BMS employees stating: "We also have Keith Ferdinand presenting . . . at the ABC meeting on VPIs [vasopeptidase inhibitors], so we need to *decide on content and work with him.*" PX 329 (emphasis added).
> . An e-mail from William Maher of BMS to others including Coniglio stating that Ferdinand [will give a] presentation at [*131] [the] ABC symposium, March 11
>
> > -- High level overview of Vanlev, survey of clinical data, possibly a single slide of -037; aggregate S&E summary, possibly by ethnicity . . . Ferdinand need[s] to get a Q&A briefing. We will have both Black and Ferdinand at Adv. Board meeting on March 8, so there will be a chance to talk with them there.
> PX 340.
>
> . The testimony of Ami Knoefler, of the "Vanlev Public Affairs Team," that the Public Affairs Team was not involved with Ferdinand's ABC presentation, but that she had discussed the content of that presentation with Tony Coniglio of the Global Brand Group: "I recall discussion with Tony Coniglio about Dr. Ferdinand's presentation as it related to the efficacy and safety results of omapatrilat clinical trials." DX 37, Knoefler Dep. 213:5-9.
> . Finally, Plaintiff has evidence that some of Ferdinand's slides were the same as those shown at the AHA Symposium by Drs. Weber and Pouler and at the ACC by Black and Dahlof. Compare PX 244 with DX 294; PX 222; PX 56; PX 69; PX 70.

The question is whether this evidence, taken together, is sufficient to support the inference that BMS "reviewed and approved," and therefore adopted Ferdinand's [*132] challenged statement at the ABC event. The Knoefler testimony, at most, shows that Coniglio had an interest in what Ferdinand said at the conference but it fails to suggest BMS's "entanglement" with Ferdinand's statement. The evidence that Ferdinand would be briefed on Q & A for the event is also irrelevant to the adoption question because the challenged statement is part of slide and was not an unscripted comment made during a Q & A session. The evidence that Drs. Black, Weber, Dahlof and Ferdinand had some of the same slides, may permit the inference that the doctors had two-way communications with one another regarding their respective presentations, but it does not permit the inference that one or all of the Defendants reviewed and approved the slides' content. The best, most probative evidence on this issue is the Coniglio e-mail which is unambiguous about the fact that individuals at BMS "decided on [the] content [of Ferdinand's ABC presentation] and worked with him." PX 329. This e-mail alone permits the inference that BMS reviewed and approved the slides presented by Ferdinand at the conference. Therefore, should a jury find that BMS adopted Ferdinand's statement, well [*133] *after* the February 11, 2000 meet-

ing with the FDA, when individuals at the company had actual notice of the FDA's concern about angioedema, Plaintiff has adduced sufficient evidence of conscious misbehavior or recklessness to prove scienter in connection with statement number ten.

However, Defendant's raise an additional issue with respect to Ferdinand's statement, which is that the statement was made at a medical conference and, according to Defendants, there is no evidence that it was reported to the market. Defs.' 56.1. PP476. Plaintiff counters with the following two pieces of evidence:

> . A "Credit Suisse, First Boston" report titled "ACC Meeting Wrap Up" devoting its lead story the Vanlev data presented at the ACC; stating that "additional efficacy and safety data for Vanlev could provide later claims in heart failure and add provide [sic] support for its hypertension launch for in [sic] the third quarter . . . Vanlev was shown to have tolerability similar to lisinopril." PX 520:2.
> . Evidence that SG Cowen held a conference call to discuss the news emerging from the ACC meeting. PX 521 ("Data will be presented [at the ACC] on Bristol-Myers Squibb's Vanlev and [*134] Plavix . . . .").

Assuming that the ABC is considered a sub-part of the larger ACC conference, this evidence would be sufficient for a jury to infer that the Ferdinand presentation was reported to the market. Defendants are unaided by *In re Cypress Semiconductor Securities Litigation, 891 F. Supp. 1369, 1378 (N.D. Cal. 1995)* which they cite for the proposition that a "statement [made] to a group of . . . sales persons . . . [and] not a public gathering . . . [such that] the information did not enter the market and affect the stock price . . . .[such that] plaintiffs cannot establish reliance on this statement" is not actionable. Defs.' Mem. at 22 n.16. Unlike Cypress, here, there can be no dispute that the ACC and ABC are public gatherings and that Ferdinand's presentation was covered in analysts' reports.

Defendants argue, further, that the cited reports are insufficient because the reports do not mention the Ferdinand statement explicitly. Reply at 21. But the Court is persuaded by Plaintiff's logic, presented in a different context but equally applicable here: On the question of materiality Plaintiff argued that,

> in an efficient market, [*135] one does not expect significant stock price reactions -- positive or negative -- when a defendant's misstatements or omissions do not announce *new* information to the market and instead only confirm investors' prior expectations . . . Here, Defendants' misstatements and omissions on the ten days in question did not announce any new information, but rather released information that simply confirmed the market's expectations about Vanlev's safety profile and chances for FDA approval. . . . Accordingly, investors had no reason to revise their estimates of the value of BMS's stock . . . .

Opp'n at 24 n.10.

Similarly, in this context, one does not expect reports of misstatements or omissions that do not announce *new* information to the market, reports that only confirm investors' prior expectations, to be extensive and detailed. It is clear from Plaintiff's evidence that Ferdinand's statement was received by reporters and analysts. But it would be a mistake require that analysts explicitly mention Ferdinand's statement when reporting on the ACC conference. To the extent that Ferdinand's presentation only reinforced the "good news" about Vanlev, it could have served to maintain [*136] the share price at an artificially high level. See, supra, § III.B.1. Ferdnaind's statement indeed confirmed the positive statements that Black, Weber, Ringrose and BMS had announced earlier. Because Ferdinand announced no *new* information it is not necessary that analysts' reports mention the statement explicitly, it is enough to prove that the presentation was included in an event that analysts attended and reported upon.

For all of the above reasons, it is clear that Defendants acted with scienter when they adopted statement number ten and that the statement was indeed disseminated to the market. **Summary judgment will be denied with respect to statement number ten.**

The evening following Ferdinand's presentation, at a dinner held in connection with the ACC Symposium on or about March 12, 2000, Dahlof gave a presentation entitled, "Clinical Benefits of Effective Blood Pressure Lowering," in which he showed and explained a slide entitled "Common Clinical AEs in Placebo-Controlled Studies (%)." DX 294:OMA0002096, OMA0002108. The slide states that Vanlev has been observed to have a "tolerability profile similar to amlodipine, lisinopril, and losartan," and Dahlof told [*137] his audience that VANLEV was observed to have a "tolerability profile at least comparable to existing agents." DX 94:OMA0002096, OMA0002108 (challenged statement number eleven).

As with the other statements by non-defendant physicians, Defendants argue that they did not adopt Dahlof's statement. Plaintiff cites the following four pieces of evidence to support its contrary contention:

> . Evidence that Dahlof contracted with BMS and received payments for work on Vanlev at least as early as November 1998. See PX 519;
> . evidence that the statement was made at a dinner for Vanlev investigators and key-opinion leaders, organized and chaired by BMS in connection with the ACC symposium. PX 453;
> . evidence that some of Dahlof's slides were the same as those shown by other physicians at events in connection with Vanlev. Compare DX 294 with PX 56; PX 69; PX 70; and
> . evidence that Dahlof's safety message conformed to BMS's Q&A and Product Summary of Vanlev as revised for the ACC events. Compare DX 294:OMA0002108 with PX 517:OMA0054762.

See also Plaintiff's Visual Aids Distributed at Oral Argument held on June 20, 2005 at 73-79.

First of all, in [*138] evaluating this evidence, the fact of a contractual relationship between BMS and Dahlof is, as explained above, insufficient in itself to permit an inference of adoption. By the same token, evidence that BMS sponsored the event at which the alleged misstatement or omission was made is also insufficient -- it does not show any "entanglement" with the content of the statement or two-way communication about the statement, as it does not suggest review or revision. As with Ferdinand's slides, evidence that some of Dahlof's slides were the same as those shown by other physicians at other events in connection with Vanlev only permits the inference that the doctors communicated with one another regarding the content of their respective presentations. This evidence fails to implicate Defendants -- and it is particularly unhelpful since Plaintiff failed to cite the particular slides, within these several, long, and technical presentations, which are allegedly identical. Lastly, the evidence that Dahlof's safety message conformed to BMS's Q&A and Product Summary of Vanlev, perhaps shows that Dahlof got his information from BMS but it does not permit an inference that Defendants reviewed and [*139] approved Dahlof's message. Contrast this evidence with the Coniglio e-mail, discussing Ferdinand's statement, which unambiguously stated that individuals needed to "decide on content [for the ACC presentation] and work with him." PX 329. None of the Dahlof evidence rises to this level.

Plaintiff argues that one reason why the evidence of adoption or endorsement is so scant here, is that Ferdinand and Dahlof were never deposed. Plaintiff filed an affidavit pursuant to *Fed. R. Civ. P. 56(f)* to depose Ferdinand and Dahlof, and has directed the Court's attention to *Korea Express USA, Inc. v. K.K.D. Imports, Inc., 2002 U.S. Dist. LEXIS 27862, No. Civ. 00-2940 (WHW), 2002 WL 31954077 at *9 (D.N.J. Aug. 28, 2002)*, which urges that [HN43] "district courts have a duty under *Rule 56(f)* to ensure that the parties have been given a reasonable opportunity to make their record complete before ruling on a motion for summary judgment." The Court, however, agrees with Defendants' position that Plaintiff had reasonable, ample opportunity to take these depositions before the close of fact discovery and that they declined to do so despite the fact that Plaintiff had expressly challenged [*140] statements attributed to Ferdinand and Dahlof in their First Amended consolidated class action complaint, filed to this date, nearly three years ago. DX 247: PP81-83. It is clearly the case that Judge Hughes' decision to place reasonable limits on discovery cannot excuse Plaintiff's failure to seek a deposition that, as they claim, is critical to the Plaintiff's case.

Thus, notwithstanding Plaintiff's request to depose Ferdinand and Dahlof, **Defendants' Motion, with respect to Dahlof's statement number eleven, will be granted** because Plaintiff has adduced insufficient evidence that any of the Defendants adopted or endorsed the statement.

Summing up, Defendants' Motion for Summary Judgment will be granted with respect to statements five and nine because Plaintiff has failed to adduce evidence that would permit an inference of conscious misbehavior or recklessness, scienter, on the part of Defendants. Defendants' Motion for Summary Judgment will be granted with respect to statement one because it is neither false nor misleading. Defendants' Motion will also be granted with respect to statements six and eleven because there is insufficient evidence for a jury to find that the [*141] **Defendants adopted or endorsed the statements. Finally, for the reasons set forth fully above, Defendants motion will be denied with respect to statements two, three, four, seven, eight, and ten.**

III.D. Statements in the Second Class Period: March 22, 2001 through March 20, 2002

The challenged statements in the Second Class Period all relate to Vanlev's potential to be a blockbuster and they are all indisputably forward-looking. They were all made after the results of the OCTAVE (hypertension)

trial were known to the company but before the results of the OVERTURE (heart failure) trial were known. Defs.' 56.1 P352. Plaintiff contends, and Defendants do not deny, that Defendants had the unblinded results of the OCTAVE study in September 2001 and that the results established that the Vanlev angioedema rate, at a lowered 10mg starting dose was 2.2%, and that based on internal BMS benchmarks, developed in consultation with the FDA, these results did not meet BMS's safety hypothesis for Vanlev. PX 157; DX 212.

The Statements (with emphasis added): On or about November 7, 2001, BMS issued a press release entitled, "Bristol-Myers Squibb Announces Unprecedented Plan to Submit [*142] Global Regulatory Filings for Five Potential Blockbusters Within 12 Months -- Accelerated Pipeline Expected to Produce Three New Products Per Year"-- in which it was stated that, "over the next 12 months, Bristol-Myers Squibb Company (NYSE:BMY) plans to submit an unprecedented number of regulatory submissions, including global regulatory filings for five new potential blockbuster compounds." DX 285; 245 (challenged statement number twelve). Dolan was quoted as stating, "Our 'Strategy for Growth' plan, which was announced just one year ago, has already delivered significant results" and,

> during the past year, the company has been quite visible in the area of acquisitions and divestitures. The organization has also been aggressively focused on efforts to accelerate and enrich our future pipeline. As a result of these efforts, we believe we have the products that will allow us to achieve our goal of launching three potential blockbuster products a year for several years starting in 2003 and we are hopeful that the first of these products may launch in 2002.

DX 285; 245 (challenged statement number thirteen).

On or about December 13, 2001, BMS issued a press release [*143] entitled "Bristol-Myers Squibb Provides EPS Guidance for 2002 - Company to Refile Vanlev TM Hypertension Application with FDA on December 14." DX 293. Dolan was quoted in the press release as stating: "We are optimistic about the five new medicines that we are filing for regulatory approval in a 12-month period." DX 293 (challenged statement number fourteen). The text of the press release issued the same day stated, "The company has submitted - or plans to submit - five new drug filings ... The new drug filings include Vanlev TM (omapatrilat), which the company intends to refile with the U.S. Food and Drug Administration (FDA) on December 14, 2001 for treatment of hypertension. The company hopes the FDA will approve Vanlev during the second half of 2002." DX 293 (challenged statement number fifteen).

Next, on or about January 15, 2002, BMS issued a press release in which Dolan was quoted as stating, "the newly-combined clinical and pharmaceutical development organization will succeed in advancing record number of innovative blockbuster brands they are poised to deliver into the marketplace, among them Vanlev TM (omapatrilat) for hypertension and heart failure." PX 262:1 (challenged [*144] statement number sixteen).

Defendants argue that Plaintiff's case with respect to Second Class Period statements should be dismissed on all of the following grounds: (1) each of the statements was true, or was reasonably believed to be true based on available facts, Defs. Mem. § III.A.1; (2) there was no statistically significant price increase at the time the statements were made (this argument was addressed, and dismissed, in this Opinion, supra, § III.B.1); (3) the statements are all inactionable "soft information," or forward-looking statements; and (4) they each came with adequate cautionary language.

III.D.1.a. "Safe Harbors" for Forward Looking Statements

Plaintiff argues, initially, that all of the Second Class Period statements survived the Court's 2004 Opinion and Order as well as Judge Brown's 2001 Opinion and Order, and that these prior Opinions are the law of the case with respect to the statements' actionability. See Opp'n at 27; Defs. Mem. at 18-19; 2004 Opinion at 69-71; 2001 Opinion at 23-24; see also *Vosgerichian v. Commodore Int'l Ltd, 1998 U.S. Dist. LEXIS 17681, No. CIV. A 92-CV-4867, 1998 WL 966026, at *4 (E.D. Pa. Nov. 6, 1998)* (finding court's ruling on [*145] issue of "puffery" on motion to dismiss binding for purposes of summary judgment). The 2001 and 2004 Opinions may be the law of the case, but these rulings do not foreclose dismissal of the statements at this stage of the litigation, for other reasons.

Specifically, in its 2004 Opinion this Court found that

> even though these statements are forward-looking in that they refer to the "*potential* blockbuster" or "*potential* first-in-line" status of Vanlev and even if these statements were accompanied by adequate cautionary language, Plaintiff adequately alleges that Defendants had enough in-

> formation regarding the OCTAVE trial design and results to know that this status would not be attained.

2004 Opinion at 63 (citing *In re Prudential Sec. Ltd. Partnerships Litig., 930 F. Supp. 68, 72 (S.D.N.Y. 1996)* ("The doctrine [safe harbor or bespeaks caution] provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon is one foot away")). At this juncture, then, it is appropriate to consider whether Plaintiff's allegations are supported by sufficient [*146] evidence to permit an inference that Defendants had enough information to know, or to be reckless in not knowing, that their forward-looking statements were false or misleading. Whether Plaintiff has the burden of proving actual knowledge or recklessness depends on whether the forward-looking statements fall into common law or statutory "safe harbors."

As discussed above, the PSLRA contains a statutory safe harbor for forward-looking written or oral statements that are "identified as a forward-looking statement[s], and [are] accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." *EP Medsystems, Inc. v. EchoCath, Inc., 235 F.3d 865, 872-873 (3d. Cir. 2000)* (citing *15 U.S.C.A. § 78u-5(c)(1)(A)(i) (West Supp.2000)*).

Additionally, statements "not identified as forward-looking as required by the safe harbor provision," may still be protected under the bespeaks caution doctrine as adopted by the Third Circuit in *In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357 (3d Cir.1993). EP Medsystems, 235 F.3d at 873.* [*147] "Under this doctrine, 'cautionary language, if sufficient, renders the alleged omissions or misrepresentations immaterial as a matter of law.'" Id. Cautionary language "must relate directly to that on which investors claim to have relied. . . . [A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation will not suffice . . . cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions . . . which the plaintiffs challenge." Id. (citations omitted). As with the PSLRA safe harbor, the bespeaks caution doctrine will not immunize forward-looking statements that are made with actual knowledge of their falsity at the time they are made. See id. (citing with approval *Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 (1st Cir. 1996)).*

Defendants argue that statement number sixteen is "cautionary" on its face because it says that BMS is only *"poised"* to deliver a record number of blockbuster brands. Defs.' 56.1 P521; Defs.' Mem. at 19-20; Reply at 18. This argument is unpersuasive for the same reason that [*148] it was unpersuasive with respect to statement number five, see, supra, § III.C.2.b. As with statement number five (and at the risk of repetition), Defendants inappropriately place dual reliance on the word *"poised."* The statement is forward-looking because *"poised"* means essentially the same things as "about to" or "is planning to"-- to this extent, there is no problem. The problem arises when the single word that makes the statement "forward-looking," is also cited as the statement's "accompanying cautionary language." As explained previously, if every "forward-looking word" is also considered "inherently cautionary," every forward-looking statement would fall into the safe harbors. The safe harbors' requirement for meaningful cautionary language would be a meaningless. At any rate, it can hardly be argued that the word "poised," even if it is cautionary, is "substantive and tailored to the specific future projections." *EP Medsystems, 235 F.3d at 873.* For these reasons, Neither the PSLRA nor the bespeaks caution doctrine apply to statement number sixteen. Proof of recklessness will, therefore, suffice to defeat summary judgment with respect to this statement. [*149]

On the other hand, statements twelve, thirteen, fourteen and fifteen, were accompanied by the following cautionary language (all emphasis added):

. "This press release contains 'forward-looking statements' as that term is defined in the Private Securities Litigation Reform Act of 1995. The forward-looking statements include *statements regarding the company's research pipeline concerning product development and product potential. These statements are based on management's current expectations and involve significant risks and uncertainties that may cause results to differ materially from those set forth in the statements. There can be no guarantees with respect to pipeline products that future clinical studies will support the data described in this release, that products will receive regulatory approvals, or that they will prove to be commercially successful.* These and other risk factors are discussed in Exhibit 99 to the company's 2000 Annual Report on Form 10-K and in the company's periodic reports on Form 10Q. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise." DX [*150] 245:6 (accompanying statements twelve and thirteen) (emphasis added).

. "This press release includes certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other

things, statements relating to goals, *plans and projections regarding the company's financial position, product development and business strategy.* These statements may be identified by the fact that they use words such as 'anticipate,' 'estimate,' 'expect,' 'intend,' 'plan,' 'believe,' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. *Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. These factors include, among other things, market factors, competitive product development, governmental regulations and legislation, patent positions and litigation.* For further details and a discussion of these and other risks and uncertainties, see [*151] the company's Securities and Exchange Commission filings, including the company's 2000 annual report on Form 10-K. The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise." DX 293:3 (accompanying statements fourteen and fifteen) (emphasis added).

. Additionally, in the company's 2000 Form 10-K, BMS explained that "this Form 10-K Annual Report, and other written or oral statement[s] that the Company makes from time to time, contain certain 'forward-looking' statements all of which are subject to risks and uncertainties . . ..These statements are likely to relate to, among other things, the Company's goals, plans and projections regarding its financial position, results of operations, market position and product development, which are based on current expectations that involve in Herat [sic] risks and uncertainties, including factors that could delay, divert or change any of them in the next several years . . ..Although it is not possible to predict or identify all factors, they may include the following: . . . New government laws and regulations, such as . . . (ii) changes in the FDA [*152] and foreign regulatory approval processes that may cause delays in approving, or prevent the approval of new products . . . *Difficulties and delays inherent in product development, manufacturing, and sale, such as (i) products that may appear promising in development may fail to reach market for numerous reasons, including efficacy or safety concerns, the inability to obtain necessary regulatory approval, and the difficulty or excessive cost to manufacture* . . . No assurance can be given that any goal or plan set forth in forward looking statements can be achieved and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. The Company undertakes no obligation to release publicly any revisions to forward looking-statements as a result of future events or developments." DX 330: PAG00017140 (emphasis added).

Plaintiff argues that none of this language is adequate to qualify the challenged statements for any of the safe harbors because it is "neither sufficient nor meaningful." Opp'n at 33-36. It is just boilerplate, Plaintiff argues, because it could apply to any drug and is not tailored to address the issues related to [*153] Vanlev. Id. at 34-35.

Indeed, the excerpted cautionary language does not include a specific statement that "after OCTAVE, the FDA will likely not approve the Vanlev NDA." It does, however, state generally that "there can be no guarantees that products will receive regulatory approvals," "uncertainties include . . . products that may appear promising in development [but] may fail to reach market for numerous reasons, including efficacy or safety concerns." Thus, here, the general representations of blockbuster potential were mitigated by the discussion of the several factors that could impact the commercial success of pipeline drugs. Since the statements on which Plaintiff relies speak to Vanlev's *general* potential to be a blockbuster brand, the uncertainties enumerated relate sufficiently, and are sufficiently specific, to be "meaningful," and to warn investors of the risks. See *In re Adams Golf, Inc. Securities Litigation, 381 F.3d 267, 279 (3d Cir. 2004)* (finding that cautionary language was adequate for safe harbors where (1) plaintiff alleged that the material omission was the potential for "retail oversupply affecting golf industry retailers" and (2) [*154] the cautionary language categorized a series of specific risks facing an investor, but did not mention retail oversupply in particular; explaining that "the cautionary statements relate directly to the claim on which plaintiffs allegedly relied; and that the general representations of better business ahead were mitigated by the discussion of the several factors that could have caused poor financial results.").

For the reasons above, statements twelve, thirteen, fourteen, and fifteen come under the umbrella of the bespeaks caution doctrine and/or the PSLRA safe harbor for forward-looking statements. As such, for these statements, Plaintiff must adduce adequate evidence that the statements were made with actual knowledge that they were false, otherwise the statements are not actionable. This inquiry is related to the general question of scienter and is undertaken in the next section.

III.D.2. Scienter

III.D.2.a. Evidence of Conscious Misbehavior (or Recklessness, Statement Sixteen only)

As proof of scienter in the Second Class Period, Plaintiff has adduced evidence from two key sources. The first is an internal memo authored by Beth Seidenberg, who was at the [*155] time a senior BMS epidemiologist. The second is evidence from meeting minutes cataloging the company's conversations with the FDA about the agency's concern with angioedema, leading up to, during and after OCTAVE was unblinded. Defendants respond, arguing that even if this evidence is credited, it remains clear that Defendants reasonably thought, based on available facts, that Vanlev could have been a blockbuster for the treatment of heart failure alone. E.g., Defs.' Mem. at 25. Representative portions of the evidence are excerpted below.

III.D.2.a.i. The Seidenberg Memo

Plaintiff cites a memo e-mailed from Beth Seidenberg to Ringrose (also copied to Laurie Smaldone of BMS) as evidence that, even before the OCTAVE data was unblinded, the company knew that Vanlev would never be a blockbuster drug for the treatment of hypertension. PX 54 (dated May 30, 2000). The memo was written and reviewed before any of the challenged statements in the Second Class Period were made. In essential part, the memo reads as follows:

> We *completed* a careful review of all the results and risk factor analysis available from the hypertension and heart failure studies (still blinded). The starting [*156] dose hypothesis [later tested in OCTAVE] has some flaws (i.e.: if we combine angioedema with head and neck edema the 10mg starting dose has the same incidence as the 20mg starting dose). . . . Based on this and the desire to maximize our probability of success, we have been considering several options which might provide optimization of the positioning and market opportunity. . . . The options are briefly outlined below:
>
> . . .
>
> **Option A:**
> Accelerate OVERTURE and file First line for Heart Failure & Second Line for Hypertension at the same time. An expedited regulatory review maybe granted based on positive OVERTURE results showing mortality/morbidity benefit over enalapril. Positive OVERTURE results may also have a halo effect and help support a second-line indication for hypertension.
>
> **Option B:**
> Conduct a large ACE-inhibitor comparison study [testing 10mg dose hypothesis] to ascertain the incidence of angioedema. This would be an attempt to maintain the first line indication for Hypertension. . . . The potential outcomes are:
> . If the incidence and severity are similar between omapatrilat and enalapril . . . the results [would then] support a *first* [*157] *line claim for hypertension* which can be filed as early as 06/2001. This outcome is not likely.
> . If the incidence and/or severity are only moderately higher with omapatrilat than enalapril, the results may support a *second-line indication for hypertension* . . . filing . . . when OVERTURE is available (end [of] 2001[]). This is a more likely outcome. . . . The filing would include both a second-line indication in hypertension and a first-line indication in heart failure based on OVERTURE results.
> . [If] the incidence and/or severity are significantly higher with omapatrilat than enalapril, the results will not support use in hypertension. A claim for *treatment of heart failure only* maybe filed independently [at the] end [of] 2001[] based on OVERTURE results.
>
> **Option C:**
> The third option is to pursue a morbidity and mortality claim for hypertension . . . It should be noted that there is no pilot mortality/morbidity data showing a survival benefit for omapatrilat . . . in hypertensive patients; .hence it is not possible to predict the likelihood of showing a mortality/morbidity benefit over an ACE [inhibitor] in patients with hypertension.

PX [*158] 54:OMA0052536-39.

The Seidenberg memo would permit the following inferences: (1) the company knew that even after conducting a large scale study at a lower starting-dose, a study like OCTAVE, the most likely outcome would be that Vanlev would have only *second-line indication for hypertension;* (2) even if Vanlev were *second-line for the treatment of hypertension,* it still had the potential to be a *first-line treatment for heart failure;* (3) and the predictions made in the memo were based on review of all data that the company had on omapatrilat as of May 30, 2000 (this can be inferred from the fact that no predictions about likely outcomes were made under Option C because of the lack of clinical data).

The Seidenberg memo did not go unanswered, and it must be considered in context. By July 16, 2000, BMS was approaching a final decision to proceed with OCTAVE. DX 32 at 158. BMS's Andrew Bodnar, then Senior Vice-President of Medical & External Affairs, prepared a memorandum to Ringrose, dated July 16, 2000, which countered the conclusions and predictions of the Seidenberg memo. DX 270. In relevant part the Bodnar memo states the following:

> . . . Beth [Seidenberg's] [*159] . . . thinking has evolved significantly in [the last six weeks] in response to further clarification of the FDA's positions. . . .
> . . .
> . . . Our review of the literature from post-marketing reports and a 1994 FDA advisory led us to the conclusion that, at the 10mg starting-dose, angioedema associated with omapatrilat appeared to be comparable to the rate associated with ACE inhibitors.
> . . . In . . . discussions with the FDA, we proposed to lay out the details of a large study evaluating the blood pressure reducing efficacy of omapatrilat vs. enalapril, while, at the same time, assessing the comparative incidence of angioedema associated with the two agents. Starting from an assumption that the two drugs would show the same frequency of angioedema, we proposed to power the study to yield a 95% confidence level . . . that omapatrilat is not associated with angioedema at more than twice the rate associated with enalapril. . . . The FDA agreed, in principle with our assessment and we set out to design and consider such a trial.
> . . .
> While not stated explicitly, given the history . . . the conclusions in Beth[] [Seidenberg's] memo . . . were clearly predicated on a number [*160] of assumptions that have subsequently not been borne out.

DX 270:OMAP 0085802.001-002. Bodnar's memo clearly contradicts the conclusions in the Seidenberg memo and it explains, in detail not quoted above, reasons why Bodnar thought Seidenberg was wrong.

While Bodnar's memo does not wipe out the possible inference that the Seidenberg memo was credited by individuals at BMS, it does show that executives at BMS were faced with conflicting assessments. When coupled with the fact that even Seidenberg was optimistic about the possibilities for Vanlev in treating heart failure, it does not appear that any reasonable jury could find that the speakers in the Second Class Period were reckless, no less, speaking with actual knowledge that their statements were false.

Plaintiff's proof is, however, more extensive. In addition to the Seidenberg memo, Plaintiff has offered evidence from a number of sources to prove exactly how much BMS knew about the FDA's views of Vanlev. This evidence is reviewed in the next section.

III.D.2.a.ii. Evidence from BMS Meetings with the FDA Regarding Angioedema

According to an internal BMS e-mail written by Dan MacNeil, a member of the Vanlev team, [*161] in a meeting between the FDA and BMS held on March 17, 2000, before any data from OCTAVE was available, the FDA raised "strong concern about the four subjects in our database who required intubation for angioedema." PX 133. MacNeil further stated that the FDA, as first discussed in the February 11, 2000 meeting, had

> not seen intubation in clinical trial databases before. It is the severity rather than the incidence of angioedema which is the chief concern, and an issue for approvability . . . They would like some assurance that this severity is not unique to omapatrilat. The FDA are willing to discuss the issue on a weekly basis. Our database searches have become even more important.

Id.

In addition, official meeting minutes indicate that the FDA started the meeting stating that in the past it was enough for an agent to just lower blood pressure, now "there are many antihypertensive agents currently available that effectively lower blood pressure and have a low safety risk." DX 57:OMA0076749. "The increased safety risk needs to be addressed prior to approval." DX 57:OMA0076750. During the meeting, with respect to the risk benefit balance of Vanlev, the FDA stated further: [*162]

> If there is an increased risk with omapatrilat, then the question is whether omapatrilat offers a greater benefit than what is currently available or a benefit to a specific subpopulation that the others do not

> offer. The increased risk would be more acceptable if omapatrilat saved lives. Even if it were shown that omapatrilat is better at lowering blood pressure than other antihypertensive agents (i.e., lowers more mm mercury than other approved agents do), this may not be sufficient to warrant approving omapatrilat. It might be that the dose ranges of the other agents were not fully explored and that at higher doses, the other agents would have the same effect. If omapatrilat addressed an unmet medical need, such as effectively lowering blood pressure in patients who are refractory to other antihypertensive agents, the safety concerns would be more acceptable. However, we are not convinced that omapatrilat addresses such a need.

DX 57:OMA0076750-OMA0076751.

Shortly thereafter, on March 30, 2000, two weeks before the 8-week OCTAVE data was available, BMS requested another meeting with the FDA to discuss BMS's hypothesis that the angioedema seen with Vanlev could be [*163] controlled by initiating treatment at a 10 mg dose and then titrating them to higher doses. PX 228:OMA0941661-OMA0941664. In official meeting minutes the FDA concluded

> The Division's position at the Advisory Committee Meeting will probably be that there is some phenomenon with some tested regimens of omapatrilat that show more serious angioedema than did the other ACE inhibitors, at least for the dose regimens that were studied. The Division was skeptical that [BMS's] present data and analysis are sufficiently compelling to assure us that starting at 10mg doses completely addresses the angioedema safety concerns.

Id. at PX 228 OMA0941664. Then, on April 13, 2000, the FDA reiterated its concerns about Vanlev's higher rate of angioedema, "especially of serious angioedema, a potentially lethal adverse effect. Such a serious adverse effect does not appear acceptable for an antihypertensive agent, unless the agent had an unequivocal advantage, such as considerably greater efficacy, etc., over other antihypertensive therapy, including combination therapy." DX 59:OMA0868532. The FDA also reiterated that the "overall rate of angioedema with [Vanlev] appears to be 5-10 times [*164] higher than the rate for the ACE inhibitors and the cases more severe," and stated that

> the Agency has defined a finite acceptable risk with respect to the incidence and severity of angioedema for the ACE inhibitors. With appropriate warnings in the label, the ACE inhibitors are useful antihypertensive tools with an acceptable safety risk. The risk appears higher for [Vanlev] with no advantage to offset it.

DX 59:OMA0868532-34.

The FDA also stated that BMS's "suggestion that a lower (10mg) starting-dose will yield a lower rate [of angioedema was] plausible and somewhat supported by the data, but . . . the retrospective nature of the analysis left too much uncertainty given the importance of the issue." DX 59:OMA0868532. The FDA displayed a particular concern over the discrepancy of angioedema between Vanlev and ACE-inhibitor-treated African-American patients.

At a meeting on April 13, 2001, BMS senior-management discussed whether BMS should refile the Vanlev NDA with the eight-week or 24-week data. PX 325; PX 448; PX 394. The handwritten notes of Dr. Seidenberg noted that the "Risk vs benefit unblind now risk higher than benefit; more obligation to announce." [*165] DX 44:243-248; PX 325. She also noted that the "Pattern of angioedema combined data does not fulfill prior hypotheses not favorable." Id.

The whole of the above detailed evidence, unequivocally, permits an inference that Defendants had *actual knowledge* that Vanlev would never be a *blockbuster* for the treatment of *hypertension* -- the combination of the FDA's view of the risks and benefits, coupled with the disappointing results of OCTAVE are indisputably sufficient to support such an inference.

Still, Plaintiff's case in the Second Class Period comes down to whether Defendants had actual knowledge that the drug *could not possibly* be blockbuster for the treatment of heart failure. Defendants have produced substantial evidence that BMS insiders, based on contemporaneous internal projections, could have reasonably believed that the drug had blockbuster potential for heart failure. Both Plaintiff and Defendants' evidence is discussed in the following section.

III.D.2.a.iii. Evidence Concerning Vanlev as a Treatment for Heart Failure

Defendants' Evidence: Defendants cite, among other things, the following evidence that BMS internal projections showed that [*166] Vanlev had blockbuster potential solely for the treatment of heart failure:

. an unidentified chart dated (in handwriting) September 22 (year not marked) predicting that, on the high end, the world wide market for Vanlev as a heart failure treatment could exceed a billion dollars by 2005 and two billion dollars by 2007, variables cited are clinical trial outcomes; success in pricing negotiations; and market share (the most optimistic projections assume a 50% market share in the United States, 38% International), Defs.' 56.1 P167 (citing DX82: OMA 1751098);
. a chart from presentation materials titled, "Worldwide Medicines, 2002-2005 Strategic Plan, Financial Review, Executive Committee," dated July 12, 2001, predicting that if the OVERTURE results are positive, in a heart failure only launch of Vanlev, BMS could achieve 755 million in net sales by 2003; 2.1 billion by 2004; and 3.5 billion by 2005, id. (citing DX 85:OMA 1766286); and
. a chart from a presentation given by Anthony Coniglio, of the Global Marketing Group, titled "VANLEV: Brand Plans: Base and Optimized Plans Across Three Potential Scenarios," dated August 22, 2001, forecasting that Vanlev sales in 2005 [*167] as an indication for heart failure alone, could exceed those in the alternative scenarios, id. (citing DX86:OMA 1712156).

Defendants also cite experts' and analysts' reports indicating that Vanlev had promise to be a blockbuster for the treatment of heart failure, but these, in contrast to contemporaneous internal projections, shed little light on the state of mind of individuals at the company. Likewise, projections made after any of the challenged statements were made are irrelevant.

Plaintiff's Evidence: Plaintiff offers the following five pieces of evidence to suggest that Defendants had actual knowledge (or in the case of statement sixteen, were reckless in not knowing) that Vanlev could not have been a blockbuster for the treatment of heart failure alone. See Pl.'s 56.1 PP516-27, 574.

First, Plaintiff cites a BMS, internal record of contact with Dr. Stockbridge of the FDA. The record was made by Andrew Waclawski, a BMS regulatory liaison, on or about January 11, 2002. The record post-dates all but one of the challenged statements -- statement sixteen. Plaintiff's *Rule 56.1* statement excerpted this report as follows:

> In that conversation [with Waclawski], [*168] Dr. Stockbridge explained his opinion that an FDA Advisory Committee meeting would not be needed to discuss the refiled NDA. As related in a Record of FDA Contact written by Waclawski:
>
> > [Stockbridge] said that if the data presented (i.e. the OCTAVE data summary) at the meeting (of September 19) were accurate, he did not think the Agency would need the advice of an Advisory Committee. . . . Dr. Stockbridge said that he did not think that [OVERTURE] would matter much. He said that if the hypertension data presented already were accurate 'we were in a pretty deep hole and it was 'hard to imagine' how the heart failure data could help.

Pl.'s 56.1 P574 (citing PX 200:OMA 1786197-98). In actuality, the document cited states, further, that:

> I [Waclawski] pointed out that this heart failure study could show a mortality benefit versus an ACE inhibitor. [Stockbridge] acknowledged that this might have some impact.
> On the other hand, [Stockbridge] said that the data from the heart failure study, if positive against an ACE inhibitor would be important for a heart failure indication, since we have actually measured benefit. He went on to note that in the hypertension [*169] studies, we still only measure a surrogate of benefit. He also said that in the case of a positive heart failure study the need for an Advisory Committee was not obvious, if only because a [sic] *the assessment could be fairly clear-cut in favor of a heart failure indication.*

PX 200:OMA 1786197 (emphasis added). Considered in full, this evidence supports an inference that Defendants had a basis to believe that the FDA supported approval of Vanlev for the treatment of heart failure, if OVERTURE yielded positive results.

Second, Plaintiff cites an internal, BMS e-mail exchange between Larry Reed, Thomas Speigel, Michael Jahn and Helen Torley, in which Speigel requests "op-

erations input on [whether] congestive heart failure [CHF] is an Opportunity Seeking Blockbuster [OSB], [as a] standalone indication." Pl.'s 56.1 P514 (citing PX 425: OMA 0584296). Reed responded that "CHF does not readily show blockbuster potential . . . As a standalone indication it does not feel comfortable to believe that a compound solely for CHF has OSB potential." PX 425: OMA 0584296. Reed explains briefly his reasons for this view and goes on to say that "nevertheless, given the needs [*170] of the business, I am very open to exploring any realistic possibilities. . . . given the current treatment paradigm, thinking about a compound for CHF as an add-on to existing therapy [ACE inhibitors or VPI] seems most prudent." Id.

Viewing this evidence at its most damaging to Defendants, the most that it proves is that there were individuals at BMS who did not think that Vanlev could be a blockbuster for the treatment of heart failure. When considered in context, alongside Defendants evidence that *others* at BMS thought that Vanlev *could* be a blockbuster for the treatment of heart failure, this e-mail does not permit the inference that speakers believing one side over the other were reckless in relying upon that belief.

Third, Plaintiff cites a Vanlev forecast prepared in November 27, 2000, discussing a heart-failure-only scenario, showing that Vanlev, with a 25% greater benefit than enalapril in the treatment of heart failure would still only earn $ 400 million sales after eight years of marketing. Pl.'s 56.1 P515 (citing PX 378, not citing page number in exhibit). The chart to which Plaintiff seems to be referring, however, also forecasts earnings should Vanlev [*171] demonstrate a 30-50% greater benefit than enalapril. In this scenario, internal BMS projections were that Vanlev could achieve nearly $ 800 million in sales. Now, this figure might not satisfy Plaintiff's definition of what is a "blockbuster," but it surely is close enough to make it reasonable for someone, speaking close to a year later, to state that the drug could be a blockbuster.

Fourth, Plaintiff cites the testimony of Dr. Packer, who was a consultant with BMS. Pl.'s 56.1 at P516 (citing DX 38 165:13-20). As recounted by Dr. Packer:

> Q. Did anyone with Bristol-Myers Squibb express disagreement with your views [that the heart failure marketplace is actually underestimated and is in fact larger than the hypertension marketplace]?
> A. It would be fair to say that they found my views to be interesting, but not necessarily reflective of their views. They always thought of hypertension as being more important than heart failure. And we continued to discuss this for months and years.

Id. This testimony, however, does not permit the inference that it would be reckless to believe (and to state) that a heart failure treatment could be a blockbuster. Even assuming [*172] that the heart failure market was not underestimated, and even if it could never be greater than the hypertension market, Packer's testimony still says nothing about whether a drug for the treatment of heart failure could be a blockbuster. This evidence is irrelevant to the assertions in the challenged statements.

Fifth, and finally, Plaintiff relies heavily on the expert report of Dr. Allan Detsky. Plaintiff relies on the report to prove the following:

. Following OCTAVE, even if OVERTURE showed a 20% proportionate reduction in the risk of death compared with enalapril, Vanlev could not have achieved "blockbuster" status. Pl.'s 56.1 at P517 (citing PX 14:12-13).
. Dr. Detsky reviewed internal BMS forecasts from a variety of sources and concluded that "New molecular entities (NME) would be expected to take 22% of the market [of worldwide heart failure sales], thus even if Vanlev captured the entire 22%, sales would only have been about $ 500 million. Id. at P518 (citing PX 14:13; PX 472: VAS00140341).
. Dr. Detsky did not believe that the ability to raise the price of Vanlev, if it were only marketed for heart failure, would improve its ability to be a blockbuster. [*173] Id. at P519 (citing PX 14:13)
. After OCTAVE, the angioedema issues for the hypertension indication would extend to heart failure because: (1) patients, providers and physicians "are bound to extrapolate; (2) the drug would likely have a "black box warning;" (3) patients with heart failure also have hypertension, so the markets cannot be totally segregated. Id. at P520 (citing PX 14:14). Dr. Detsky further opined, "based on the examples of Serzone and Seldane and his expertise, that Vanlev's peak sales as a treatment for heart failure . . . would be reduced by at least 70% and as much as 90% . . . due to the results of OCTAVE." Id. at P521 (citing PX 14:15).

Assuming, for the sake of argument, that the Detsky testimony and report were admitted as proof of all of the above propositions (Detsky is the subject of one of Defendants' Daubert Motions) this evidence still fails to suggest that anyone at BMS shared Dr. Detsky's views. Nor does it suggest that anyone at BMS was even aware of Detsky's views. On the question of whether individuals at BMS would have been reckless in believing that Vanlev could be a blockbuster for heart failure, Detsky's

views are irrelevant. [*174] While it is true that Dr. Detsky's report purports to be based on internal BMS projections -- and so, arguably, individuals at BMS could have extrapolated, as did Dr. Detsky -- nevertheless, the BMS projections relied on by Detsky did not stand alone: There is sufficient evidence that other BMS projections were more optimistic about the heart failure indication and the Detsky evidence tells us nothing about which set of projections influenced the speakers in the Second Class Period.

III.D.2.a.iii. Analysis of the Evidence of Scienter in the Second Class Period and Conclusions

Statement Fifteen: Statement fifteen falls into one or both of the safe harbors for forward-looking statements. As such, for the statement to be actionable, Plaintiff would have to show that Defendants acted with actual knowledge that the statement was false or misleading. See, supra, § III.D.1. But the Court need not reach this issue, because with respect to this statement, Plaintiff has failed to make the threshold showing that the statement was false or misleading. The evidence may show that Defendants knew Vanlev could never be a *blockbuster* for the treatment of *hypertension*. But statement [*175] fifteen does not say that the drug would be a blockbuster at all -- not for hypertension nor anything else.

Statement fifteen says that BMS planned to refile the Vanlev NDA for the treatment of hypertension and that it hoped the NDA would be approved. Plaintiff's evidence does not show that BMS, after OCTAVE, abandoned its intention to refile the Vanlev NDA. Nor does the evidence show that BMS had no hope that Vanlev would be approved, even if it meant the drug would have a black box warning. In point of fact, BMS did refile the Vanlev NDA after OCTAVE. Pl.'s 56.1 P567. Based on the evidence, a reasonable jury could not find that statement number fifteen was false or misleading. **For this reason, Defendants' Motion, with respect to statement fifteen, will be granted.**

Statement Sixteen: Because statement sixteen was not accompanied by meaningful cautionary language, see, supra, § III.D.1, Plaintiff need only adduce evidence sufficient to permit the inference that Defendants were reckless in not knowing that the statement was false or misleading.

Statement sixteen, while it mentions hypertension, is not about Vanlev exclusively as a treatment for hypertension. The statement [*176] expresses Dolan's view that *Vanlev* would be a blockbuster *brand* for the treatment of hypertension and heart failure, combined. See PX 262. Consider the statement's context: Dolan was quoted in a press release announcing that Elliot Sigal would be assuming the position of Senior VP of Global Clinical and Pharmaceutical Development. Id. Dolan was expressing his confidence in Sigal's leadership in advancing the Vanlev brand. Id. The entire press release is devoted to Sigal's qualifications. No portion of it is technical or scientific and there is no discussion of Vanlev, other than the challenged statement. Id. Simply, when Dolan named "Vanlev (TM) (omapatrilat) for hypertension and heart failure" among a list of three other drugs and their respective indications, it is clear that he was merely identifying the brand in more detail. He was not specifying that this brand would a be a blockbuster for each of these two indications.

Considering all of the evidence in a light most favorable to the Plaintiff it appears that individuals at BMS, at this point in time, still held the reasonable belief that Vanlev had the potential to be blockbuster for the treatment [*177] of heart failure. A reasonable jury could not infer from the evidence that this belief and statements expressing this belief were reckless. [HN44] Reckless conduct is "highly unreasonable (conduct), involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care." *Ikon, 277 F.3d at 666*. Here, reckless conduct is not at all evident. **For this reason Defendants' Motion will be granted with respect to statement number sixteen.**

Statements twelve, thirteen and fourteen: Because statements twelve, thirteen and fourteen were each accompanied by meaningful cautionary language, see, supra, § III.D.1, and are protected by the bespeaks caution doctrine (and/or the PSLRA safe-harbor provisions), Plaintiff must adduce evidence that Defendants had actual knowledge that these statements were false.

If the evidence is insufficient to prove that a belief in the blockbuster potential of Vanlev was reckless, then *a fortiori,* the same evidence cannot support the inference that the statements were knowingly false. Defendants have produced evidence sufficient to show that they reasonably believed that Vanlev could be [*178] a blockbuster for the treatment of heart failure alone. Plaintiff has failed to show that Defendants had actual knowledge to the contrary and no one of these statements so much as mentions hypertension. **For this reason, Defendants' Motion will be granted with respect to statements twelve, thirteen and fourteen. None of the challenged statements in the Second Class Period survive summary judgment.**

III.E.1. Individual Liability of Defendants Dolan and Heimbold, *Section 20(a)*

Plaintiff alleges that Defendants Heimbold and Dolan are liable as controlling persons under *Section 20(a)*. See Opp'n 45-49. Plaintiff does not maintain any allegation that Ringrose was a control person. Opp'n at 45. Defendants contend that Plaintiff cannot support its alle-

gations with evidence that Heimbold and Dolan were "culpable participants" in the alleged fraud. Defs.' Mem. at 28.

[HN45] "*Section 20(a)* creates liability for 'controlling persons' in a corporation, *15 U.S.C. § 78t(a)*, and imposes joint and several liability upon anyone who 'controls a person liable under any provision of' the Exchange Act." *P. Schoenfeld Asset Management LLC v. Cendant Corp., 142 F. Supp. 2d 589, 623 (D.N.J. 2001)* [*179] (citing *Rochez Brothers, Inc. v. Rhoades, 527 F.2d 880, 885 (3d Cir. 1975)*). "To maintain a claim under *§ 20(a)*, the plaintiffs must establish (1) an underlying violation by a controlled person or entity, (2) that the defendants are controlling persons, and that they were 'in some meaningful sense culpable participants in the fraud perpetrated by controlled persons.'" Id. Defendants do not deny that at certain periods Heimbold and Dolan were control persons with the ability to control BMS, see Defs' Mem. at 29-30. As established above, BMS has potential 10b-5 liability for statements two, three, four, seven, eight and ten. See, supra, § § III.C.c. - C.d.

Only one surviving statement, statement ten, made on March 11, 2000, was made during Dolan's tenure as a control person. Mr. Dolan did not become CEO of BMS until the Second Class Period. Opp'n at 46. Prior to becoming CEO, Dolan was president of BMS (named in late January 2000). Id. So, at the time Dr. Ferdinand made the actionable statement, Dolan had only been president of BMS for approximately five weeks. Simply, it strains credulity to infer that in those five weeks, Dolan had the opportunity [*180] to internalize the alleged institutional knowledge of BMS and to "culpably participate" in Dr. Ferdinand's allegedly fraudulent statement at a medical conference. "Culpable participation" can be satisfied on summary judgment where facts show the control person "knew or should have known that [the] primary violator . . . was engaged in fraudulent conduct." *Dietrich v. Bauer, 126 F. Supp. 2d 759, 765-66 (S.D.N.Y. 2001)*. Here, no reasonable jury could reach such a conclusion. Plaintiff has detailed evidence of Dolan's involvement with Vanlev -- but none of this evidence predates statement number ten, so it is all irrelevant to the issue of Dolan's individual liability.

Second, with respect to Heimbold, Plaintiff relies on the following relevant evidence:

> . Heimbold became President of BMS in October 1992, and Chairman in June or July 1995. DX 36 19:8-20:25 Heimbold's job "was to be responsible for the affairs of the Company." Id. at 175.
> . Heimbold chaired the Corporate Issues Committee ("COC") in 1999 and 2000, which typically met the day before each board meeting in order to brief Heimbold on major areas within the company. DX 32: 27-28. The COC consisted [*181] of the heads of the various corporate staff functions, as well as the heads of the WWM and the head of Research & Development (Ringrose). The COC was the most senior group of people at BMS other than members of the Board of Directors. Id. at 26:17-27; 27:20-29:5.
> . Heimbold also chaired a management committee which reviewed BMS's business on a monthly basis. DX 36:70. At the September 13, 1999 Management Committee meeting, Heimbold and other Committee members discussed Vanlev and noted that the "blockbuster" launch of Vanlev was a critical success factor for BMS. Id. at 81-82; PX 301.
> . Heimbold generally reviewed and approved press releases in which he was quoted discussing issues of regulatory approval and Vanlev. DX 36 at 90.
> . BMS's President of WWM, who had direct oversight of Vanlev, reported to Heimbold. PX 28 168:21-24.
> . Reviewing the recommendation from the pharmaceuticals research group, Heimbold made the ultimate decision to withdraw the Vanlev NDA in April 2000. DX 36:104-05. He, along with Dolan, also made the decision to proceed with OCTAVE. DX 36: 104-05.

Once again, "culpable participation" is evident if these facts demonstrate that Heimbold knew [*182] or should have known that the primary violator, here BMS, was engaged in fraudulent conduct, but Heimbold did nothing to prevent it. See *Dietrich v. Bauer, 126 F. Supp. 2d 759, 765-66 (S.D.N.Y. 2001)*. Heimbold presents a much closer case than Dolan.

On the one hand, the statements remaining in the case, all from the First Class Period, are very specific -- generally discussing the results of the Vanlev clinical trials. There is no evidence that Heimbold reviewed and approved any of the individual statements specifically. On the other hand, however, because there are numerous statements to the same effect -- "Vanlev has a favorable side-effect profile compared to other ACE inhibitors"-- a reasonable jury could infer that these statements were part of a more general message for the promotion of Vanlev, of which, Heimbold certainly would have been aware. Moreover, based on Heimbold's involvement in

the daily affairs of the corporation, it can be inferred that he had knowledge of the angioedema issue, which was discussed extensively among individuals and teams involved with Vanlev. So, on balance, it appears that Plaintiff has adduced sufficient evidence for a jury to [*183] find Heimbold liable under *Section 20(a)*. **Defendants Motion will be denied with respect to Mr. Heimbold's liability under *Section 20(a)*.**

III.E.2. *Section 10(b)* Individual Liability

Plaintiff's cause of action against Defendants Ringrose and Dolan individually, under *Section 10(b)*, must be dismissed because the statements made by Ringrose and Dolan, statements five, thirteen, fourteen, fifteen, and sixteen, did not survive summary judgment.

E. Plaintiff's Motion to Strike Portions of the Summary Judgment Record

Because none of the evidence challenged in Plainitff's Motion to Strike was relied upon in this Opinion, the Motion will be dismissed as moot.

V. Conclusion

In an Order accompanying this Opinion and dated the same, Defendants' Motion for Summary Judgment will be granted with respect to statements **one,** Compl. P52; **five,** Compl. P65; **six,** Compl. P58; **nine,** Compl. P73; **eleven,** Compl. P82; **twelve,** Compl. P148; **thirteen,** Compl. P148; **fourteen,** Compl. P150; **fifteen,** Compl. P151; and **sixteen,** Compl. P155.

Defendants' Motion for Summary Judgment will be denied with respect to statements **two,** [*184] Compl. P53; **three,** Compl. P50; **four,** Compl. P53; **seven,** Compl. P66; **eight,** Compl. P70; and **ten,** Compl. P83.

Defendants' Motion for Summary Judgment with respect to the individual liability of Dolan and Ringrose, will be granted; and with respect to the individual liability of Heimbold, the Motion will be denied.

Plaintiff's Appeal of Judge Hughes's Order and Opinion of April 28, 2005, Dkt. No. 229, will be denied.

Plaintiff's Motion to Strike Material from the Summary Judgment Record, Dkt. No. 299, will be dismissed as moot, and decision with respect to Daubert Motions will be reserved for a later date.

Stanley R. Chesler, U.S.D.J. /s/

Dated: August 17, 2005

ORDER

CHESLER, District Judge

This matter having come before the Court on the Motion for Summary Judgment, pursuant to *Federal Rule of Civil Procedure 56*, of Defendant Bristol-Myers Squibb Company and individual defendants Peter R. Dolan, Charles A. Heimbold, Jr., and Peter S. Ringrose; and

Plaintiff's Motion to Strike Material from the Summary Judgment Record, filed on May 13, 2005; and

Plaintiff's Appeal of Judge Hughes's Order and Opinion [*185] denying leave to file a Third Amended Consolidated Class Action Complaint, filed on May 12, 2005;

For the reasons set forth the Opinion accompanying this Order and dated the same;

IT IS HEREBY on this 17th, day of August, 2005, ORDERED that:

(1) Defendants' Motion for Summary Judgment, Dkt. No. 201, will be GRANTED with respect to statements **one,** First Amended Consolidated Class Action Complaint ("Compl.") P52; **five,** Compl. P65; **six,** Compl. P58; **nine,** Compl. P73; **eleven,** Compl. P82; **twelve,** Compl. P148; **thirteen,** Compl. P148; **fourteen,** Compl. P150; **fifteen,** Compl. P151; and **sixteen,** Compl. P155; and

(2) Defendants' Motion for Summary Judgment, Dkt. No. 201, will be DENIED with respect to statements **two,** Compl. P53; **three,** Compl. P50; **four,** Compl. P53; **seven,** Compl. P66; **eight,** Compl. P70; and **ten,** Compl. P83; and

(3) Defendants' Motion for Summary Judgment, Dkt. No. 201, with respect to the individual, *Section 20(a)* and *10(b)*, liability of Defendants Dolan and Ringrose, will be GRANTED; these Defendants are hereby DISMISSED from the case; and

(4) Defendants' Motion for Summary Judgment, [*186] Dkt. No. 201, with respect to the individual, *Section 20(a)*, liability of Defendant Heimbold, will be DENIED;

(5) Plaintiff's Appeal of Judge Hughes's Order and Opinion of April 28, 2005, Dkt. No. 229, will be DENIED, and

(6) Plaintiff's Motion to Strike Material from the Summary Judgment Record, Dkt. No. 236, will be DISMISSED as moot.

Stanley R. Chesler, U.S.D.J./s/